Supreme Court, U.S.
FILED

NO. 04 579

OCT 29 2004
OFFICE OF THE CLERK

In The Supreme Court of the United States

WAYNE CHARLES OKEN,

Petitioner,

v.

THE MONSANTO COMPANY, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR WRIT OF CERTIORARI

Stuart Calwell
Counsel of Record
THE CALWELL PRACTICE
Law and Arts Center West
500 Randolph Street
Charleston, West Virginia 25302
(304) 343-4323

Alex McLaughlin
THE CALWELL PRACTICE
178 Chancery Row
Morgantown, West Virginia 26505
(304) 291-5223

Counsel for Petitioners

RECEIVED
NOV 1 - 2004
OFFICE OF THE CLERK
SUPREME COURT, U.S.

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, VA 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

QUESTION PRESENTED

Which, if any, state law personal injury claims are preempted by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136–136y?

LIST OF PARTIES TO THE PROCEEDING

WAYNE CHARLES OKEN,

Appellant,

v.

THE MONSANTO COMPANY, THE SOLARIS GROUP, SCOTTS COMPANY, DOW AGROSCIENCES LLC, DOWELANCO, THE DOW CHEMICAL COMPANY, EPCO, INC., ROFAN SERVICES INC., HOME DEPOT U.S.A., INC., THE A.B.C. COMPANY, ET AL.,

Appellees.

TABLE OF CONTENTS

Page

QUESTION PRESENTED i

LIST OF PARTIES TO THE PROCEEDING ii

TABLE OF CONTENTS iii

TABLE OF AUTHORITIES v

OPINIONS BELOW 1

STATEMENT OF JURISDICTION 1

STATUTORY PROVISIONS INVOLVED 1

STATEMENT OF THE CASE 2

REASONS FOR GRANTING THE PETITION 5

I. Introduction 6

II. This Court Should Grant Review to Resolve the Conflict Among the Lower Courts Regarding Whether FIFRA Preempts Certain Design Defect Claims 10

A. The Eleventh Circuit's Forbidden Inquiry Test 10

B. Consumer Expectations-Based Claims Under the Manufacturer's Choice Test 14

III. This Court Should Grant Review to Resolve the Conflict Between the Eleventh Circuit's Forbidden Inquiry Test and This Court's Prior Precedent on FIFRA 15

IV. This Court Should, In the Alternative, Grant Review Pending the Resolution of Bates, Vacate the Judgment of the Court of Appeals, and Remand for Further Consideration 16

CONCLUSION 17

APPENDIX

TABLE OF AUTHORITIES

Page(s)

CASES

Andrus v. AgrEvo USA Co.,
178 F.3d 395 (5th Cir. 1999) 7-8

Arnold v. Dow Chemical Co.,
110 Ca. Rptr. 2d 722 (Cal. Ct. App. 2001) 14

Bates v. Dow AgroSciences LLC,
332 F.3d 323 (5th Cir. 2003), *cert. granted*,
124 S. Ct. 2903 (2004) ..... *passim*

Chemical Specialties Mfrs. Ass'n v. Allenby,
958 F.2d 941 (9th Cir. 1992) 8

Cipollone v. Ligget Group, Inc.,
505 U.S. 504 (1992) 10, 11

Ferebee v. Chevron Chemical Co.,
736 F.2d 1529 (D.C. Cir. 1984) 9, 10

Lescs v. William R. Hughes, Inc.,
168 F.3d 482,
1999 WL 12913 (4th Cir. 1999), *cert. denied*,
528 U.S. 1119 (2000) 14, 15

Netland v. Hess & Clark, Inc.,
284 F.3d 895 (8th Cir. 2002) 7

Oken v. Monsanto Co.,
218 F. Supp. 2d 1361 (S.D. Fla. 2002) 12

Oken v. Monsanto Co.,
371 F.3d 1312 (11th Cir. 2004) 13

Papas v. Upjohn Co., cert. denied sub nom,
985 F.2d 516 (11th Cir. 1993)
Papas v. Zoecon Corp.,
510 U.S. 913 (1993) 7, 10, 11, 12

Pitts v. Dow Chemical Co.,
859 F. Supp. 543 (M.D. Ala. 1994) 9, 11

Sleath v. W. Mont Home Health Servs., Inc.,
16 P.3d 1042 (Mont. 2000), *cert. denied sub nom,*
Dow AgroSciences LLC v. Sleath,
534 U.S. 814 (2001) 10, 11

Wisconsin Public Intervenor v. Mortier,
501 U.S. 597 (1991) 8, 16

Worm v. American Cyanamid Co.,
5 F. 3d 744 (4th Cir. 1993) *7*

STATUTES

7 U.S.C. §§ 136–136y ..... *passim*

7 U.S.C. § 136v 1, 11

7 U.S.C. § 136v(a) 8, 9, 15, 16

7 U.S.C. § 136v(b) ..... *passim*

28 U.S.C. § 1254(1) 1

Petitioner respectfully requests that this Court grant his writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

OPINIONS BELOW

The district court's opinion granting the motion for summary judgment of respondents Dow AgroSciences LLC, The Dow Chemical Company, Rofan Services, Inc., and Epco, Inc. (collectively, "the Dow defendants") is published at 218 F. Supp. 2d 1361. The opinion of the court of appeals affirming the district court's grant of summary judgment for all respondents is published at 371 F.3d 1312.

STATEMENT OF JURISDICTION

The court of appeals entered its order and opinion on June 4, 2004. The court of appeals entered its order denying Petitioner's petition for rehearing on August 2, 2004. Petitioner invokes this Court's jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

7 U.S.C. § 136v provides:

Authority of States

(a) **In general.** A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent that it does not permit any sale or use prohibited by this subchapter.

(b) **Uniformity**. Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

(c) **Additional uses**. (1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this subchapter and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator.

STATEMENT OF THE CASE

Petitioner, Wayne Charles Oken, purchased two bags of Ortho Dursban Lawn & Garden Insect Control from Respondent Home Depot U.S.A., Inc. ("Home Depot"). Petitioner, a homeowner, read the label and applied the two bags to his lawn using a two-wheeled spreader. As he spread the lawn and garden pesticide, a mist of powder arose and clung to his skin. Shortly thereafter, petitioner began to experience the signs and symptoms of acute cholinergic poisoning. He required immediate hospitalization, where he had to be intubated to assist his breathing, and has suffered severe neurological problems since.

Ortho Dursban Lawn & Garden Insect Control, as the name suggests, was a product intended and marketed for use by homeowners and sold in retail outlets such as Home Depot. "Dursban" is a trademark of Respondent Dow AgroSciences LLC ("Dow"), and Dow supplied the product's active ingredient. Respondent The Monsanto

Company ("Monsanto") took the active ingredient that Dow supplied (actually Dow supplied a product called "Dursban HF," which contains some inactive ingredients as well), applied it to an inert carrier (such as peanut hulls or corn grit), and packaged it for sale. In industry parlance, Dow is known as the "basic manufacturer" and Monsanto is known as the "formulator." Dow and Monsanto were both integral participants in the design and marketing of Ortho Dursban Lawn & Garden Insect Control.

Petitioner filed suit against Home Depot, an unknown distributor ("A.B.C. Company") and numerous entities related to Dow and Monsanto in the Circuit Court of the 17th Judicial Circuit, Broward County, Florida on April 12, 2001 to recover damages for his personal injuries. The complaint stated strict products liability claims against each of the defendants for selling an unreasonably dangerous product with manufacturing, design, and warning defects. It also stated negligence claims against each defendant for failure to stop the sale of Ortho Dursban Lawn & Garden Insect Control. The complaint stated additional negligence claims against the Dow and Monsanto defendants arising out of their manufacture and design of the product.

The case was removed to federal district court in Ft. Lauderdale, Florida on August 15, 2001. Following removal, while discovery was ongoing, the Dow defendants filed a motion for summary judgment averring that Petitioner lacked evidence to support his allegations of manufacturing defect and negligent manufacturing, and that the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. 136–136y ("FIFRA") preempted the remainder of his claims. Petitioner responded that FIFRA does not preempt any common law claims. He also emphasized that, even if FIFRA does preempt those claims premised on failure to warn, at least his allegation that the active ingredient in Ortho Dursban Lawn & Garden Insect Control

is too dangerous for use by nonprofessionals or around residences is an attack on the product's design rather than its label, as it would make no sense to label a do-it-yourself lawn and garden pesticide as "not for use by homeowners."

The district court granted the Dow defendants' summary judgment motion as to the manufacturing claims for lack of evidence, and granted the Dow defendants' motions as to the remaining claims on the basis of FIFRA preemption. In holding that Petitioner's design defect claims under Florida law were preempted by FIFRA, the district court focused on what Florida law would require a jury to consider rather than the specific restrictions on product sales and uses that Petitioner sought to enforce through his damages action. The court held that the two tests for design defectiveness under Florida law, the risk-utility test and the consumer expectations test, both require the jury to take into account the warnings given to the public and that, therefore, under prevailing Eleventh Circuit law the claims were preempted.

Petitioner appealed the district court's ruling on FIFRA preemption to the United States Court of Appeals for the Eleventh Circuit, arguing that FIFRA did not preempt any of his claims. Petitioner again urged that his allegation that the active ingredient in Ortho Dursban Lawn & Garden Insect Control was too dangerous to be handled by nonprofessionals or used around residences supports the inference that a do-it-yourself lawn and garden pesticide containing the ingredient is defectively designed rather than mislabeled. The Eleventh Circuit affirmed the district court. The court held that it was bound by the prior panel precedent rule to hold that FIFRA preempted claims premised on failure to warn. As to Petitioner's negligent and defective design claims, the court shifted focus, albeit ever so slightly, from forbidden jury considerations to inescapable causal connections: Because, presumably,

Petitioner would not have used the product had he been given adequate warnings (hypothetically speaking, something along the lines of "this product is too dangerous to use unless you are a trained professional or under the supervision of a trained professional"), the court found that his claims are based at least in part on inadequate labeling, and are therefore preempted by FIFRA. Petitioner subsequently requested a rehearing; it was summarily denied.

Wayne Charles Oken respectfully petitions this Court to review the holding of the Eleventh Circuit.

REASONS FOR GRANTING THE PETITION

On June 28, 2004, this Court granted a petition for writ of certiorari to review the holding of the United States Court of Appeals for the Fifth Circuit in *Bates v. Dow AgroSciences LLC*, 332 F.3d 323 (2003). *See Bates v. Dow AgroSciences LLC*, 124 S. Ct. 2903 (2004). The question presented by petitioners in that petition for writ of certiorari is limited to FIFRA preemption of state law crop injury claims. Petitioner Wayne Oken presents a similar question regarding FIFRA preemption of personal injury claims. There is just as much confusion among the lower courts about which state law personal injury claims, if any, FIFRA preempts. The extent to which individuals can be compensated for injuries caused by pesticides is an issue that is every bit as important as the extent to which farmers may be compensated for crop damage. Moreover, the facts and venue of this case provide this Court with an ideal opportunity to provide direct answers to two particularly nettlesome questions: (1) whether design defect claims predicated on risk-utility tests are preempted because one factor among many is the adequacy of the warnings accompanying the product, and (2) whether design defect

claims predicated on consumer expectations are preempted because the inquiry involves consideration of the warnings.

Finally, the Eleventh Circuit's FIFRA preemption analysis and its holding in this case stand at one end of the FIFRA spectrum. The Eleventh Circuit's "forbidden inquiry" analysis conflicts with this Court's own precedent and provides a stark contrast to the reasoning and analysis of those courts less inclined to find preemption. Petitioner Wayne Oken respectfully requests that this Court grant his Petition for Writ of Certiorari as a companion to *Bates* to identify, to the extent possible, the scope of FIFRA preemption of personal injury claims, and to clarify the proper analysis for questions of FIFRA preemption. In the alternative, Petitioner respectfully requests that this Court grant his petition pending review of the Fifth Circuit judgment in *Bates*, vacate the judgment of the Eleventh Circuit in this case, and remand for further consideration in light of the judgment and opinion of this Court in *Bates*.

I. *Introduction*

The fact that Petitioner's actual, specific allegations of wrongdoing and defect were ignored in favor of purely abstract, formalistic considerations in both published opinions below shows just how important it is that this Court has decided to step into the morass of FIFRA preemption jurisprudence and clarify it. Conjecture is currently the cornerstone of FIFRA preemption analysis in most United States courts of appeals, although there is significant disagreement as to what the proper object of conjecture is. The Eleventh Circuit's "forbidden inquiry" analysis turns on a court's conjecture as to what a jury might be called upon to *consider* in the course of its deliberations. If it is at all possible that a damages claim might require a jury to consider the warnings, the claim is preempted. Under the Eleventh Circuit's FIFRA jurisprudence, states are

forbidden from undertaking such an inquiry. *See Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993), *cert. denied sub nom. Papas v. Zoecon Corp.*, 510 U.S. 913 (1993) ("*Papas II*") ("[Plaintiffs'] allegations . . . require the finder of fact to determine whether, under state law, [Defendant] adequately labeled and packaged its product. This inquiry is precisely what section 136v forbids."). In the Eleventh Circuit, whether a state law is preempted by FIFRA section 136v(b) depends not on whether a manufacturer is required to change the label to comply with the state-imposed duty on the manufacturer or restriction on its product, but whether the state *considered* the adequacy of the label required under FIFRA in deciding to impose the additional duty or restriction.

Other circuits have embraced a FIFRA preemption test that turns on the court's conjecture as to how a manufacturer would respond to the imposition of liability predicated on certain allegations. If the manufacturer would probably change the label, then the claim is preempted; if the manufacturer would probably choose to change the product, then the claim is not preempted. *See Worm v. American Cyanamid Co.*, 5 F. 3d 744, 747–48 (4th Cir. 1993) ("*Worm II*") (holding that one key factor to FIFRA preemption analysis is "whether one could reasonably foresee that the manufacturer, in seeking to avoid liability for the error, would choose to alter the product or the label"); *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 900 (8th Cir. 2002) (citing *Worm II*, 5 F.3d at 747–48, for the same proposition); *Andrus v. AgrEvo USA Co.*, 178 F.3d 395, 399

(5th Cir. 1999).[1] This "manufacturer's choice" test is necessarily a more fact- and allegation-specific test than the Eleventh Circuit's forbidden inquiry test. The manufacturer's choice test requires a court to predict how a manufacturer is likely to respond to liability predicated on the specific allegations. The forbidden inquiry test looks only at the formal elements of the claims and defenses to determine what kinds of facts a jury or other fact finder may have to consider.

Still other courts, including this Court, have carefully considered the interaction between FIFRA subsections 136v(a) and 136v(b) and found that the preemptive provision in 136v(b) is a limitation not on the States' right to make independent determinations about the adequacy of a pesticide's label, but on the duties that states can impose on applicators, manufacturers, formulators, and sellers of pesticides. A state can independently determine that pesticide's label is inadequate, but any effort to limit the harm caused by that inadequacy must be in the form of a regulation or restriction of the use or sale of the pesticide. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 614 (1991) (noting that section 136v(a) "acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow pre-emptive overlap might occur"); *Chemical Specialties Mfrs. Ass'n v. Allenby*, 958 F.2d 941, 944 (9th Cir. 1992) (upholding against a FIFRA preemption challenge a positive state enactment requiring point-of-sale or other notices warning consumers of carcinogenicity and observing

---

[1] In the opinion that this Court recently granted certiorari to review, the Fifth Circuit transformed this question from whether the manufacturer would change the product (not preempted) or the label (preempted) into whether the manufacturer would change the product or the label (both preempted) or do something else altogether. *See Bates v. Dow AgroSciences LLC*, 332 F.3d 323, 329 n. 9 (5th Cir. 2003).

that "[o]ther than regulating labels, states are left free to impose whatever restrictions they may wish"); *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541 (D.C. Cir. 1984) (holding that "if a state chooses to restrict pesticide use by requiring that the manufacturer compensate for all injuries or for some of these injuries resulting from the *use* of a federally registered pesticide, federal law stands as no barrier") (emphasis in original). This analysis focuses on the choices that are available to the States under 136v(a). Although it has mostly been used, when it has been used at all, to address questions about whether positive enactments are preempted, nothing requires that limitation of its application.

The Eleventh Circuit's rigid adherence the forbidden inquiry test is not just contrary to the logic of circuits that follow the manufacturer's choice test. It produces different results, sometimes dramatically, in those instances where the adequacy of the label is *relevant* to an asserted claim or defense but is not the basis of the claim. Two of the three most important such instances are squarely presented in this case: (1) consumer expectations tests for design defect, and (2) risk-utility tests for design defect that treat the adequacy of the label as one factor.[2] More importantly, the forbidden inquiry test is plainly contrary to this Court's declaration that the States retain the authority under FIFRA to ban mislabeled products.

---

[2] The third instance is where the label's adequacy might be relevant to an available affirmative defense. *See Pitts v. Dow Chemical Co.*, 859 F. Supp. 543 (M.D. Ala. 1994) (holding claims preempted because jury would need to consider label in evaluating affirmative defense of assumption of risk).

II. *This Court Should Grant Review to Resolve the Conflict Among the Lower Courts Regarding Whether FIFRA Preempts Certain Design Defect Claims*

Courts have split over which, if any, design defect claims are preempted by FIFRA. The Eleventh Circuit held in the case before this Court that FIFRA preempts any personal injury claim, including a claim of defective design, in which the warnings would be considered by a fact-finder or in which the warnings can be assigned even a partial causal role in the injury. At the other end of the spectrum, the United States Court of Appeals for the District of Columbia Circuit and the Supreme Court of Montana have both held that FIFRA doesn't preempt any common law damages actions. *See Ferebee*, 736 F.2d 1529; *Sleath v. W. Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow AgroSciences LLC v. Sleath*, 534 U.S. 814 (2001).

A. The Eleventh Circuit's Forbidden Inquiry Test

The Eleventh Circuit was one of the first courts to consider FIFRA preemption after this Court's holding in *Cipollone v. Ligget Group, Inc.*, 505 U.S. 504 (1992), that common law damages actions can qualify as state-imposed "requirements" within the meaning of an express preemption provision. In *Papas v. Upjohn Co.*, 985 F.2d 516, 518 (11th Cir. 1993) ("*Papas II*"), the court concluded that FIFRA preempted claims alleging that a manufacturer "failed to warn users that its product contained certain harmful chemicals and failed to inform users to take appropriate precautionary measures." That conclusion is by itself unremarkable, as most courts that have considered the

question since *Cipollone* have agreed.[3] The court's reasoning, however, is quite remarkable. The court did not base its decision on the assumption that liability premised on such conduct would force the manufacturer to comply with additional or different state-imposed requirements for labeling. Rather, the court found that the "allegations . . . require the finder of fact to determine whether [the manufacturer] adequately labeled and packaged its product." 985 F.2d at 518. The court found that it was this "inquiry" itself – not the imposition of any duties – "that section 136v forbids." *Id.*

Confined to the facts of *Papas II*, the significance of the difference between its forbidden inquiry test and a premise-of-liability test or a manufacturer's choice test is not readily apparent. However, the forbidden inquiry test has subsequently underpinned extraordinarily sweeping interpretations of the reach of FIFRA section 136v(b)'s express preemption clause. In *Pitts v. Dow Chemical Co.*, 859 F. Supp. 543 (M.D. Ala. 1994), the court observed that, "because defendants have raised the affirmative defense of assumption of the risk, the jury will be called upon to weigh the risks posed by Dursban TC against the warnings provided to determine if those warnings are sufficient to apprise users of health risks." 859 F. Supp. at 551. The court relied heavily on the reasoning of *Papas II* in concluding that the claims are preempted by FIFRA section 136v solely because of considerations that may be invoked by an affirmative defense. "For this court to draw a distinction between claims and affirmative defenses, however, would be contrary to the directives of *Papas II* that state common law actions based 'in whole or in part' on inadequate

---

[3] *But see Sleath v. W. Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow AgroSciences LLC v. Sleath*, 534 U.S. 814 (2001) (holding that FIFRA does not preempt any common law claims).

labeling are to be preempted and that a jury is to make no inquiry into the adequacy of labeling." *Id.* at 552.

The district court in the case before this Court relied on the forbidden inquiry test in finding that Petitioner's design defect claims were preempted. Under Florida law, a products liability plaintiff can prove a design defect by satisfying either of two tests: (1) a risk-utility test that includes, as one factor among many, the adequacy of warnings, and (2) a consumer expectations-based test. The district court agreed with the defendants that under either test a jury would be required to give consideration to the warnings given to the public in ascertaining the objective expectation of the public regarding the product's dangerousness. In a reflexive application of the forbidden inquiry test, the court therefore held that design defect claims arising under Florida law are preempted, without even considering the specific allegations substantiating Petitioner's design defect claims. *See Oken v. Monsanto Co.*, 218 F. Supp. 2d 1361, 1366–67 (S.D. Fla. 2002).

The court of appeals in the case before this Court introduced a new variation on the forbidden inquiry test: the inescapable causal connection test. "[Petitioner] cannot escape, however, that his injuries were caused, at least in part, by the alleged inadequacy of the label. If the label had adequately warned him of the dangers of Dursban, he contends, he would not have used the product and would

not have been injured."[4] *Oken v. Monsanto Co.*, 371 F.3d 1312, 1314–15 (11th Cir. 2004). The specific factual allegation that the active ingredient of Ortho Dursban Lawn & Garden Insect Control is too dangerous to be handled by nonprofessionals or applied around residences was not set forth in the court's opinion. The court of appeals did not consider whether a manufacturer seeking to avoid liability for selling Ortho Dursban Lawn & Garden Insect Control (a pesticide designed and marketed for use by homeowners) would alter the active ingredient or alter the warnings to include this statement: "Warning: This product contains an ingredient that is too dangerous to be handled by homeowners except under the supervision of a certified applicator." The court of appeals, following Eleventh Circuit precedent, relied instead on the formalistic reasoning underpinning the forbidden inquiry test: If the warnings

---

[4] At the risk of undermining the argument for granting this petition, it must be pointed out that the parenthetical clause "he contends" in the quote in the text is accurate only in the most technical sense. The *Dow defendants contended* that, under Florida law, a product cannot be unreasonably dangerous, no matter how dangerous it is, so long as the warnings adequately reflect the danger. Therefore, they argued, any claim proceeding under a strict liability theory is necessarily an attack on the warnings, because sufficiently strong warnings would undercut the claim that it was unreasonably dangerous. Petitioner responded that such an argument was pure sophistry. Sure, given his allegations, if Ortho Dursban Lawn & Garden Insect Control carried a warning stating that it was too dangerous for use by nonprofessionals or around residences, it *might* not be an unreasonably dangerous product. But, *Petitioner contended* – and here's where the technical accuracy creeps in – no one (which excludes Petitioner as well) would buy a do-it-yourself lawn and garden pesticide with such warnings. The point of this should be, not that the court of appeals got the specific allegations wrong, but that the Eleventh Circuit has established (two variations of) a test for FIFRA preemption that proceeds on formalistic reasoning alone, without regard to the specific allegations.

are arguably relevant – even if only because there exists some hypothetical warning that would have simultaneously rendered the product completely unmarketable and prevented this plaintiff's use of the product – the claim is preempted.

B. Consumer Expectations-Based Claims Under the Manufacturer's Choice Test

Petitioner's claim would undoubtedly have survived FIFRA *preemption* under the manufacturer's choice test. Petitioner's allegation is that the active ingredient of Ortho Dursban Lawn & Garden Insect Control is too dangerous for use by nonprofessionals or around residences. There is clearly a reasonable inference that a manufacturer not desiring to commit economic suicide would find an alternative active ingredient for Ortho Dursban Lawn & Garden Insect Control (a pesticide designed and marketed for use by homeowners) that is safe for use by nonprofessionals around residences rather than alter the warnings to advise against use by homeowners except under professional supervision. *See Arnold v. Dow Chemical Co.*, 110 Ca. Rptr. 2d 722, 736–37 (Cal. Ct. App. 2001) (relying on manufacturer's choice test in holding that FIFRA does not preempt plaintiffs design defects claim premised on California's consumer expectations test because "to warn that use would cause serious injury to children and fetuses would effectively end consumer demand for the products").

It is true that the Fourth Circuit, one of the leading proponents of the manufacturer's choice test, held in an unpublished opinion that "the existence of [FIFRA labeling] standards, especially when they relate to the content of product information, bears on reasonable expectations" in affirming the dismissal of a plaintiff's consumer expectations-based design defect claim. *See Lescs v. William R. Hughes, Inc.*, 168 F.3d 482, 1999 WL 12913, *12 (4th Cir. 1999) (mem.), *cert. denied*, 528 U.S. 1119 (2000). While the

acknowledgment of a relationship between FIFRA labeling and reasonable expectations would *mandate* preemption under the forbidden inquiry test, it did not under the Fourth Circuit's analysis. Instead, the Fourth Circuit affirmed the dismissal because, "There is no evidence that Dursban failed to meet consumer expectations." *Id.* It is beyond dispute that the existence of warnings on the label required by the United States Environmental Protection Agency ("EPA") under FIFRA *bears*, in an evidentiary sense, on just about any conceivable claim that involves a product registered under FIFRA, including a claim based on consumer expectations. The question presented in this case, and the question in dire need of resolution from this Court, is whether the fact that the existence of warnings on the EPA-approved label *bears* on those claims necessarily means that section 136v(b) *preempts* those claims.

III. *This Court Should Grant Review to Resolve the Conflict Between the Eleventh Circuit's Forbidden Inquiry Test and This Court's Prior Precedent on FIFRA*

The Eleventh Circuit's forbidden inquiry test swallows FIFRA section 136v(a), which reads: "A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent that it does not permit any sale or use prohibited by this subchapter." 7 U.S.C. 136v(a). If section 136v(b) is read to forbid the States from even *considering* the adequacy of an EPA-approved label in going about their affairs as so-called partners in the regulation of pesticides, then there is precious little regulation of the sale or use of any pesticide that it can engage in. The label contains directions for use (in both the target area sense and the how-to sense), so any efficient state regulatory scheme that sought to limit the use of a pesticide would presumably have not only considered the adequacy of the label, but also found against it.

It is not at all clear why the States would be forbidden from considering the adequacy of the EPA-label in going about their affairs, restricting and regulating uses, banning sales, etc. More to the point, the Eleventh Circuit's holding that the States are forbidden from considering the adequacy of the label is directly in conflict with this Court's holding that FIFRA section 136v(a) "acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow preemptive overlap might occur." *Wisconsin Public Intervenor v. Mortier*, 501 U.S. at 614. The forbidden inquiry analysis is all about preemptive overlap, the bigger the better. This Court has also explained that section 136v(a) sets forth the "authority explicitly conferred upon the States that might otherwise have been preempted through actual conflicts with federal law." *Id.* at 607. This Court should grant this petition to resolve the apparent conflict.

IV. *This Court Should, In the Alternative, Grant Review Pending the Resolution of* Bates, *Vacate the Judgment of the Court of Appeals, and Remand for Further Consideration*

The judgment and opinion of the Eleventh Circuit was without the benefit of this Court's analysis of FIFRA preemption pending its review of the Fifth Circuit's judgment in *Bates v. Dow AgroSciences LLC*, 332 F.3d 323 (5th Cir. 2003), *cert. granted Bates v. Dow AgroSciences LLC*, 124 S. Ct. 2903 (2004). This Court's disposition of that case is likely to shed light on, and conflict with, the Eleventh Circuit's opinion in this case. Even in the unlikely event that the disposition of *Bates* turns exclusively on questions of whether and to what extent the EPA does or does not regulate phytotoxicity, i.e., harm to target crops, that in itself would shed light on the proper analysis for personal injury claims. This Court should, at the least, grant this petition pending review of the Fifth Circuit judgment in *Bates*, vacate the judgment of the Eleventh Circuit in this case, and

remand for further consideration in light of the judgment and opinion of this Court in *Bates*.

CONCLUSION

This case raises important questions of federal law. The Eleventh Circuit's FIFRA preemption analysis conflicts with the analysis of other Circuit Courts of Appeal, especially in its treatment of consumer expectations-based design defect claims. The Eleventh Circuit's broad reading of FIFRA section 136v(b) conflicts with this Court's own precedent. This case presents an important question of federal law in its own right and would be an extremely useful personal injury companion case to the crop injury case now pending before this Court.

Respectfully submitted,

Stuart Calwell
Counsel of Record
The Calwell Practice
Law and Arts Center West
500 Randolph Street
Charleston, West Virginia 25302
(304) 343-4323

Alex McLaughlin
The Calwell Practice
178 Chancery Row
Morgantown, West Virginia 26505
(304) 291-5223

APPENDIX

TABLE OF CONTENTS

Appendix Page

Opinion of
The United States Court of
Appeals for the Eleventh Circuit,
With Attachment,
entered June 4, 2004 1

Attachment:

Appendix
undated 5

Opinion of
The United States Court of
Appeals for the Eleventh Circuit
entered August 2, 2004 9

Final Order of Dismissal of
The Honorable William P. Dimirouleas
entered September 30, 2002 11

Order Granting Defendants' Motions for
Summary Judgment of
The Honorable William P. Dimirouleas
entered September 30, 2002 13

Order Granting Dow Defendants'
Motion for Summary Judgment
Omnibus Order Re Other Motions of
The Honorable William P. Dimirouleas
entered August 26, 2002 16

[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 02-15943

D.C. Docket No. 01-07360 CV-WPD

WAYNE CHARLES OKEN,

Plaintiff-Appellant,

versus

THE MONSANTO COMPANY, THE SOLARIS GROUP, SCOTTS COMPANY, successor in interest to Monsanto Company and the Solaris Group, DOW AGROSCIENCES, LLC, DOW AGROSCIENCES, as successor in interest to DowElanco, DOWELANCO, as successor in interest to Dow Chemical Company, et al.,

Defendants-Appellees.

Appeal from the United States District Court
for the Southern District of Florida

(June 4, 2004) [Entered June 4, 2004]

Before TJOFLAT and CARNES, Circuit Judges, and CONWAY*, District Judge.

PER CURIAM:

---

* Honorable Anne C. Conway, United States District Judge for the Middle District of Florida, sitting by designation.

I.

The Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA") establishes a comprehensive regulatory scheme for pesticides. Manufacturers of pesticides must obtain Environmental Protection Agency ("EPA") approval of their products and the warning labels accompanying them, which instruct consumers on how to use the product safely. 7 U.S.C. §§ 136a(a), 136a(c)(1)(C). FIFRA contains an express preemption provision: States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required" by FIFRA. 7 U.S.C. § 136v(b).

In Papas v. Upjohn Co., 985 F.2d 516, 517, 520 (11th Cir. 1993) (Papas II), a damages action for personal injuries sustained "due to exposure to pesticides manufactured by [codefendant] Zoecon," we held that "FIFRA expressly pre-empts state common law actions against manufacturers of EPA-registered pesticides to the extent that such actions are predicated on claims of inadequate labeling or packaging." Such preemption extended to plaintiff's claims based on "negligence, strict liability, and breach of implied warranty," because "[e]ach of these claims was, in whole or in part, a claim of inadequate labeling for alleged dangers arising from exposure to the pesticides." Id. at 517. We therefore affirmed the district court's summary judgment dismissing the plaintiff's claims.

II.

The case before us mirrors Papas II. Wayne Charles Oken purchased two bags of Ortho Dursban Lawn & Garden Insect Control ("Dursban") from Home Depot U.S.A., Inc. ("Home Depot"). The Monsanto Company ("Monsanto") manufactured the Dursban, and Dow Chemical Company ("Dow") manufactured the product's active ingredient. A

warning label approved by EPA, and annexed to this opinion as an Appendix, was attached to the bags Oken purchased.

Oken read the warning label and, using a two-wheeled spreader, spread both bags, one at a time, on his lawn to control ants. As he spread the Dursban, he was exposed[1] to a "mist of powder [that] arose."[2] He soon suffered a reaction, which required extensive hospitalization and treatment.

The day before the statute of limitations would have barred this action, Oken brought this action for money damages against Dow, Monsanto and Home Depot[3] in a Florida circuit court.[4] His complaint sounded in negligence and strict liability. It alleged that Dow and Monsanto were negligent in designing and manufacturing the Dursban and in composing the warning label attached to the bags, Home Depot was negligent in selling an unreasonably dangerous product, and all three defendants were strictly liable for

---

[1] The complaint alleges that Oken "using an appropriate spreader, applied the [Dursban] ... to his lawn and garden for its intended use, and was exposed to the Dursban product." Complaint, ¶ 23 (emphasis added). Paragraph 23 is the only paragraph of the complaint that describes Oken's contact with Dursban.

[2] Oken asserted this in his Statement of Facts filed in response to the defendants' motions for summary judgment.

[3] Oken also named numerous parties related to Dow and Monsanto, and "A.B.C. Company," a fictitious entity that was never served and never appeared in this case.

[4] The applicable statute of limitations is provided by Fla. Stat. § 95.11, which states that "[a]n action founded on negligence," and "[a]ny action not specifically provided for in these statutes" shall be commenced within four years of the time the action accrues.

dispensing an unreasonably dangerous product.

The defendants removed the case to federal district court, and in their answers to the complaint, alleged that FIFRA preempted each of Oken's claims. Following some discovery, they moved the district court for summary judgment. The court granted their motion, concluding that the case was indistinguishable from, and controlled by, Papas II.[5] Oken now appeals.

III.

The adequacy of the Dursban warning label is at the heart of this case. Although Oken's complaint sounds in negligence and strict liability, we cannot ignore the critical causation element of each of these torts. For his negligence claims, Oken must show that the defendants' alleged negligence caused his injuries. For his strict liability claims, he must show that the alleged defects in Dursban caused his injuries. Oken cannot escape, however, that his injuries were caused, at least in part, by the alleged inadequacy of the label. If the label had adequately warned him of the dangers of Dursban, he contends, he would not have used the product and would not have been injured. As Papas II instructs, because all of Oken's claims are based at least in part on inadequate labeling, they are all preempted by FIFRA. 985 F.2d at 517.

Oken asks that we overrule Papas II. He argues that the Supreme Court's decision in Medtronic, Inc. v. Lohr, 518 U.S. 470, 16 S.Ct. 2240, 135 L. Ed. 2d 700 (1996), requires that we reevaluate Papas II and find that state-law causes of action based on inadequate warnings are not preempted by FIFRA. However, subsequent to the Supreme Court's decision in

---

[5] The court granted the defendants summary judgment on Oken's manufacturing defect claim for lack of evidence. Oken does not challenge the ruling in this appeal.

Medtronic, we reaffirmed Papas II in Lowe's Home Centers, Inc. v. Olin Corp., 313 F.3d 1307, 1308 (11th Cir. 2002). Because a panel of this court is not free to reconsider an issue decided by a prior panel, United States v. Steele, 147 F.3d 1316, 1317-18 (11th Cir. 1998) (en banc), we are bound by our decision in Lowe's, and must adhere to Papas II.

AFFIRMED.

APPENDIX

ORTHO(R)
Dursban(R) Lawn & Garden Insect Control
FLEA AND TICK CONTROL (Outdoors) SOIL INSECTS - European Crane Fly/Leather Jacket (larvae) and White Grubs. HOME INVADING PESTS (Outside) - Ants, Brown Dog Ticks, Cockroaches, Clover Mites, Crickets, Earwigs, Fleas, Millipedes, Sowbugs (Pillbugs), Silverfish, Spiders (including Black Widow Spiders).
HOME LAWNS - Ants, Chinch Bugs, Cutworms, Fall Armyworms, Earwigs, Crickets, Brown Dog Ticks, Fleas, Leafhoppers, Lawn Moths (Sod Webworms), Chiggers, Clover Mites, Grasshoppers, Spittlebugs, Sowbugs (Pillbugs).

DIRECTIONS FOR USE
It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ ENTIRE LABEL. USE STRICTLY IN ACCORDANCE WITH LABEL PRECAUTIONARY STATEMENTS AND DIRECTIONS.

FLEA AND TICK CONTROL (OUTDOORS)
Treat once a month beginning when pests first appear in late spring (May - June) and continue until late summer (September - October). Eliminating weeds around the home and mowing lawns frequently reduces hiding places. Dogs,

cats, their kennel or bedding area should also be treated with a registered product such as ORTHO Pet Flea & Tick Spray. In addition, if fleas or ticks are indoors on carpets or pet resting areas, use a product such as FLEA-B-GON(R) Flea & Tick Killer or ORTHO Home Pest Insect Control. Treat all three sites - outdoors, indoors, and the pet with appropriate labeled products to achieve control. If any one of these areas is missed, it can serve as a source of reinfestation.

HOW TO USE: Apply uniformly to home laws using a Drop, Broadcast, or ORTHO WHIRLYBIRD(R) Spreader. Treat when insects or signs of damage first appear. Retreat as necessary if reinfestation occurs.

Keep children and pets off treated areas until this material is washed into turf and grass is dry.

TO CONTROL: Ants, Chinch Bugs, Cutworms, Fall Armyworms, Earwigs, Crickets, Brown Dog Ticks, Fleas, Leafhoppers, Lawn Moths (Sod Webworms), Chiggers, Clover Mites, Grasshoppers, Spittlebugs, Sowbugs (Pillbugs): Apply 2½ lbs per 1,000 sq ft (40' x 25'). Immediately after application, give the lawn a light watering. See table below for suggested spreader settings.

Sod Webworms (Lawn Moths): Sod Webworm caterpillars feed on grass blades at night. Adult Webworms (Lawn Moths) emerge at dusk. They fly over the lawn laying eggs that later hatch into destructive caterpillars. Damage appears first as small brown spots which rapidly develop into large brown areas. If Lawn Moths are noticed in large numbers, or at first sign of damage, treat entire lawn.

TO CONTROL: Mole Crickets, Hyperodes (Turfgrass Weevils) European Crane Fly/Leather Jacket (larvae) and White Grubs (larvae of European Chafer, Southern Chafer and Japanese Beetle): Use 5 lbs/1,000 sq ft (see table below).

Thoroughly water immediately after application to wash the insecticide into the soil. For Mole Crickets apply in May or June when pests are small. Hyperodes (Turfgrass) Weevils: Treat suspected problem areas in mid-April and again in mid-May. White Grubs: Treat when grubs are young and actively feeding near the soil surface, usually during late July and August. Consult your Agricultural Extension Service Specialist for timing of application.

HOME INVADING PESTS: PERIMETER TREATMENT AROUND FOUNDATION (OUTSIDE) Ants, Crickets, Fleas, Sowbugs (Pillbugs), Millipedes, Earwigs, Clover Mites, Silverfish, Spiders (Incl. Black Widow Spiders), Cockroaches, Brown Dog Ticks: Apply in a band 2 to 6 ft wide around the building using an ORTHO WH1RLYBIRD(R) Spreader. Treat garbage can storage areas and outdoor pet resting areas. Do not treat pests with this product.

[Table omitted]

* One level ORTHO WHIRLYBIRD(R) Hand Spreader holds 2 lbs of product. NOTE: One level measuring cup (8 fl oz) hold 5½ oz of granules. Three cups equal approximately 1 lb of product.

[Table omitted]

STORAGE AND DISPOSAL:
STORAGE: Keep pesticide in original container. Do not put into food or drink containers. Avoid contamination of feed and foodstuffs. Store in a cool, dry place, preferably in a locked storage area.
DISPOSAL: PRODUCT - Partially filled bag may be disposed of by securely wrapping original container in several layers of newspaper and discard in trash.
CONTAINER- DO NOT REUSE EMPTY BAG. Discard bag in trash.

PRECAUTIONARY STATEMENTS
HAZARDOUS TO HUMANS & DOMESTIC ANIMALS
CAUTION: Harmful if absorbed through skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

FIRST AID: In case of skin contact, wash skin with plenty of soap and water. In case of eye contact, wash eyes immediately with plenty of water. See a doctor if irritation persists. Note to Physicians: Emergency information call 1-800-454-2333.

ENVIRONMENTAL HAZARDS: This pesticide is extremely toxic to fish, birds, and other wildlife. Do not apply directly to water. Drift and runoff from treated areas may be hazardous to aquatic organisms in adjacent aquatic sites. Cover or incorporate spills. Do not contaminate water when disposing of equipment washwaters,

NOTICE: Buyer assumes all responsibility for safety and use not in accordance with directions.

Medical Information call 1-800-454-2333
Product Information call 1-800-225-2883

Solaris(TM)

ORTHO(R), WHIRLEYBIRD(R), FLEA-B-GON(R), SOLARIS(TM) Trademarks of Monsanto Company

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 02-15943 BB

WAYNE CHARLES OKEN,

Plaintiff-Appellant,

versus

THE MONSANTO COMPANY,
THE SOLARIS GROUP,
SCOTTS COMPANY, successor in
interest to Monsanto Company
and the Solaris Group, et al.,

Defendants-Appellees.

[Entered August 2, 2004]

On Appeal from the United States District Court for the
Southern District of Florida

BEFORE: TJOFLAT and CARNES, Circuit Jueges and CONWAY*, District Judge.

PER CURIAM:

---

* Honorable Anne C. Conway, United States District Judge for the Middle District of Florida, sitting by designation.

The petition(s) for rehearing filed by appellant, Wayne C. Oken, is DENIED.

ENTERED FOR THE COURT:

/S/
UNITED STATES CIRCUIT JUDGE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 01-7360-CIV-DIMITROULEAS

WAYNE CHARLES OKEN,

Magistrate Judge Seltzer

Plaintiff,

vs.

THE MONSANTO COMPANY, THE SOLARIS GROUP, SCOTTS COMPANY; DOW AGROSCIENCES LLC, HOME DEPOT U.S.A., INC., et al,

Defendants.

[Entered September 30, 2002]

FINAL ORDER OF DISMISSAL

THIS CAUSE is before the Court *sua sponte*.

On August 26, 2002, this Court granted summary judgment in favor of the Dow Defendants, which include Dow Agrosciences LLC (a/k/a Dow Elanco), Dow Elanco (n/k/a Dow Agrosciences LLC), The Dow Chemical Company, Epco, Inc. and Rofan Services, Inc. Subsequently, on September 23, 2002, the Court granted summary judgment in favor of Defendants Home Depot, The Scott's Company and The Monsanto Company.

At this time, the only listed defendants left are the Solaris Group, a division of the Agricultural Group of the

Monsanto Company, that was never separately served with a copy of the Summons and Complaint, and the A.B.C. Company, an unknown defendant who has never been named. Due to the Court's grant of summary judgment as to all named and served defendants, this Court can provide no further relief in this case and the case is dismissed.

Accordingly, it is **ORDERED AND ADJUDGED** that the above-styled case is **DISMISSED.** All pending motions are denied as moot, and the Clerk shall close this case.

DONE AND ORDERED in Chambers at Fort Lauderdale, Broward County, Florida, this 30 day of September, 2002.

/S/
WILLIAM P. DIMIROULEAS
United States District Judge

Copies furnished to:
Ian G. Osur, Esq.
Stuart Calwell, Esq.
Douglas J. Chumbley, Esq.
Samuel Danon, Esq.
Daniel J. Gerber, Esq.
James E. Zloch, Esq.
Dean Barnhard, Esq.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 01-7360-CIV-DIMITROULEAS

WAYNE CHARLES OKEN,

Magistrate Judge Seltzer

Plaintiff,

vs.

THE MONSANTO COMPANY, THE SOLARIS GROUP, SCOTTS COMPANY; DOW AGROSCIENCES LLC, HOME DEPOT U.S.A., INC., et al.,

Defendants.

[Entered September 30, 2002]

ORDER GRANTING DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

THIS CAUSE is before the Court upon Defendant Home Depot's Motion for Summary Judgment Joining in Part Dow Agroscience's Motion for Summary Judgment [DE 124], Plaintiff's Opposition [DE 139], Defendant Home Depot's Reply [DE 140], Defendant Scott's Company's Joinder in the Dow Defendants' Motion for Summary Judgment [DE 135], and Defendant Monsanto Company's Notice of Joinder in the Dow Defendants' Motion for Summary Judgment [DE 137]. The Court has carefully considered the motions and is otherwise fully advised in the premises.

Defendants Home Depot Scott's Company and Monsanto have joined in the Dow Defendants' Motion for Summary Judgment, which this Court granted on August 26,2002. Defendants Scott's Company and

Monsanto stand in the same legal position as the Dow Defendants as manufacturers of a product that Plaintiff alleges caused him injuries. These Defendants, like the Dow Defendants, allege that Plaintiff's claims are preempted by the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136. This Court agrees with Defendants in that Plaintiff's claims, regardless of the particular label, amount to claims that Defendants failed to properly warn Plaintiff about the dangers of the product or label the product in a way that would have prevented such harm to Plaintiff.

Plaintiff's claims against Home Depot are preempted by FIFRA for the same reasons that the claims against the Dow Defendants, Scott's Company and Monsanto are preempted, even though Home Depot is a retailer as opposed to a manufacturer of the product. Plaintiff argues that he has not had sufficient discovery at this point to know whether Home Depot knew or should have known of the dangerousness of the product sold to Plaintiff and whether Home Depot was therefore negligent in failing to warn Plaintiff about such dangers. However, like Plaintiff's claims as to the other Defendants, Plaintiff's claim of negligence against Home Depot is preempted by FIFRA because Plaintiff is essentially claiming that the label on the product was insufficient and Home Depot should have made up for this insufficiency with additional warnings.

Therefore, the Court grants Summary Judgment to Defendants Home Depot, Scott's Company and Monsanto Company, referring to the law and analysis presented in its August 26, 2002 Order Granting Dow Defendants' Motion for Summary Judgment [DE 128].

Accordingly, it is **ORDERED AND ADJUDGED** as follows:

1. Defendant Home Depot's Motion for Summary Judgment Joining in Part Dow Agroscience's Motion for Summary Judgment [DE 124] is hereby **GRANTED** as to all claims against that Defendant;
2. Defendant Scott's Company's Joinder in the Dow Defendants' Motion for Summary Judgment [DE 135] is hereby **GRANTED** as to all claims against that Defendant;
3. Defendant Monsanto Company's Notice of Joinder in the Dow Defendants' Motion for Summary Judgment [DE 137] js hereby **GRANTED** as to all claims against that Defendant;

DONE AND ORDERED in Chambers at Fort Lauderdale, Broward County, Florida, this 23 day of September, 2002.

/S/
WILLIAM P. DIMITROULEAS
United States District Judge

Copies furnished to:
Ian G. Osur, Esq.
Douglas J. Chumbley, Esq.
Samuel Danon, Esq.
Daniel J. Gerber, Esq.
James E. Zloch, Esq.
Dean Barnhard, Esq.

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 01-7360-CIV-DIMITROULEAS

WAYNE CHARLES OKEN,

Magistrate Judge Seltzer

Plaintiff,

vs.

THE MONSANTO COMPANY, THE SOLAIUS GROUP, SCOTTS COMPANY; DOW AGROSC1ENCES LLC, HOME DEPOT U.S.A., INC., et al.,

Defendants.

[Entered August 26, 2002]

ORDER GRANTING DOW DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OMNIBUS ORDER RE OTHER MOTIONS

THIS CAUSE is before the Court upon the Dow Defendants' Motion for Summary Judgment [DE 65], Plaintiff's Motion for Extension of Time to Disclose Experts [DE 32], Dow Defendants' Cross Motion to Bar Plaintiff's Use of Undisclosed Expert Testimony [DE 35-2], Plaintiff's Motion for New Scheduling Order [DE 42], Dow Defendants' Cross Motion for Extension of Time of Expert Discovery Deadline [DE 55-2], and Dow Defendants' Motions to Strike Affidavits [DE 93 and 96]. The Court has carefully considered the motions and is otherwise fully advised in the premises.

In his complaint, Plaintiff brings claims under Florida law for negligence and strict liability against the Dow Defendants[1] and the Monsanto Defendants[2] for their formulation and manufacture of Ortho Dursban Lawn & Garden Insect Control, which contains the chemical Chloropyrifos.[3] Plaintiff alleges that he used the product for his garden as intended, but that it caused him severe neurological, physical and psychological injury. Complaint, ¶23. Specifically, Plaintiff alleges negligence and strict liability in the formulation (¶¶ 27a, 31a, 43, 49), manufacture (¶¶27b, 31b, 43,49),[4] and failure to warn of dangerous characteristics of Dursban (¶¶27g, 31g, 43, 49), among other allegations in those claims that relate to cither of these three possible categories of design defect, manufacturing defect, and failure to warn. See Jennings v. BIC Corporation, 181 F.3d 1250, 1255 (11th Cir. 1999) citing Ferayorni v. Hyundai Motor Co.. 711 So.2d 1167, 1170 (Fla. 4th D.C.A. 1998)(in turn citing

---

[1] These Defendants include Dow Agrosciences LLC (f/k/a Dow Elanco), Dow Elanco (n/k/a Dow Agrosciences LLC), The Dow Chemical Company, Epco, Inc. and Rofan Services, Inc.).

[2] These Defendants include Monsanto Company, the Solaris Group, and Scotts Company.

[3] Similar claims are brought against an unidentified distributor of the product, as well as against the seller of the product, Home Depot, Inc.

[4] The Court had previously denied Defendants' Motion to Dismiss the negligent testing claims in ¶ 27c and ¶31c, though it held that Florida law does not recognize an independent claim of negligent testing, and such claims are subsumed under the negligent manufacturing claims.

West v. Caterpillar Tractor Co., 336 So.2d 80 (Fla. 1976).[5]

Among other motions, the Dow Defendants filed a motion for summary judgment seeking dismissal of all claims based upon preemption by the Federal Insecticide Fungicide and Rodenticide Act ("FIFRA"), Plaintiff opposes the motion. Several other motions relate to expert discovery and submission of affidavits in opposition to the motion for summary judgment. The Court will address the issues in turn.

II. DISCUSSION

A. Summary Judgment Standard

The Court may grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on-file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed.R.Civ.P. 56(c). The stringent burden of establishing the absence of a genuine issue of material fact lies with the moving party. Celotex Corp. v. Catrett, 477 U.S. 317, 323(1986). The Court should not grant summary judgment unless it is clear that a trial is unnecessary. Anderson v. Liberty Lobby. Inc., 477 U.S. 242, 255 (1986), and any doubts in this regard should be resolved against the moving party, Adickes v. S.H. Kress & Co., 398 U.S. 144, 157(1970).

---

[5] The Court does note that Plaintiffs complaint is somewhat of a shotgun pleading, in that it does not separate out into separate claims the different theories of product liability recognized by Florida law. This lack of separation makes separate analysis of each type of claim somewhat difficult.

The movant "bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." Celotex Corp., 477 U.S. at 323. To discharge this burden, the movant must point out to the Court that there is an absence of evidence to support the nonmoving party's case. Id. at 325.

After the movant has met its burden under Rule 56(c), the burden of production shifts and the nonmoving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Electronic Industrial Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). According to the plain language of Fed.R.Civ.P. 56(e), the non-moving party "may not rest upon the mere allegations or denials of the adverse party's pleadings," but instead must come forward with "specific facts showing that there is a genuine issue for trial." Fed.R.Civ.P. 56(e); Matsushita, 475 U.S. at 587.

Essentially, so long as the non-moving party has had an ample opportunity to conduct discovery, it must come forward with affirmative evidence to support its claim. Anderson, 477 U.S. at 257. "A mere 'scintilla' of evidence supporting the opposing party's position will not suffice; there must be a sufficient showing that the jury could reasonably find for that party." Walker v. Darby. 911 F.2d 1573, 1577 (11th Cir. 1990). If the evidence advanced by the non-moving party "is merely colorable, or is not significantly probative, then summary judgment may be granted." Anderson, 477 U.S. 242, 249-50.

B. FIFRA Preemption

The Dow Defendants motion seeks summary judgment on the grounds of preemption of Plaintiff's state

law claims pursuant to FIFRA. The United States Supreme Court held in 1991 that FIFRA does not preempt the entire field of pesticide regulation, but allows state regulation of sale or use apart from labeling or packaging requirements, and "leaves ample room for States and localities to supplement federal efforts," such as an affirmative permit scheme for the actual use of pesticides. Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 612-13, 111 S.Ct. 2476, 2485-86 (1991) (holding that FIFRA did not preempt a local ordinance regulating the use of aerial spraying in applying pesticides). The Court analyzed the preemption language in FIFRA to reach this conclusion. Specifically, 7 U.S.C. § 136v (entitled "Authority of States") states that: (a) "A State may regulate the sale or use of any federal registered pesticide or device in the State, but only if and to the extent the regulation does permit any sale or use prohibited by this subchapter" and (b) "Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter."

Defendants argue that the term "requirements" includes state law actions for damages, while Plaintiff argues that it does not preclude such actions. While the Supreme Court has never answered this question in the FIFRA context, the Court has concluded in the cigarette labeling context that "requirements" may not be based upon "smoking and health . . . under State law with respect to the advertising or promotion of any cigarettes the packages of which are labeled in conformity with the provisions of this Act. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 515, 112 S.Ct. 2608, 2617 (1992). Following remand based upon Cipollone, the Eleventh Circuit held that state common law claims for negligence and strict liability that require a showing that labeling or packaging caused an injury are preempted by FIFRA because the term "requirements" in 7 U.S.C. § 136v(b) includes state common law claims. Papas v. Upjohn

Company, 985 F.2d 516, 520(11th Cir. 1993), *cert. denied*, 114 S.Ct. 300. However, claims that do not challenge the labeling and packaging are not preempted. Id. The plaintiff in Papas had conceded that each of their claims alleges in part that defendant had failed to warn users of the harmful chemicals and to take precautionary measures. Plaintiff in this case argues that he has made no such concession, and that claims that the pesticide is unreasonably dangerous regardless of labeling are not preempted.

Plaintiff principally relies upon the 1996 United States Supreme Court case of Medtronic v. Lohr, in which a 5-4 decision (with the fifth vote provided in a concurring opinion by Justice Breyer) concluded that in the Medical Device Act ("MDA"), the term "requirements" in the preemption section did not preclude all state common law damages actions. 518 U.S. 470, 489, 116 S.Ct. 2240, 2252 (1996). The majority held that because the word "requirement" in the MDA was used often in that statute it had more specific meaning than when used in the Cigarette Labeling Act. Both the plurality and the concurring opinion concluded that due to a Food & Drug Administration regulatory scheme defining preemption as involving "specific" requirements as to a device, the state personal injury action could proceed. Medtronic. 518 U.S. at 494-500, 505-507, 116 S.Ct. 2254-58, 2260-61.[6]

Plaintiff argues that if the Eleventh Circuit analyzed FIFRA preemption today, it would follow the Supreme Court's analysis in Medtronic, retreat from Papas, and

---

[6] The four justice plurality opinion also concluded that Congress could not have intended to preempt all state tort claims in the absence of a federal remedy under the MDA, without explicitly stating such preemption. Medtronic, 518 U.S. at 487,116 S.Ct. at 2251. Even in Cipollone, not all state law claims were ruled preempted.

conclude that Plaintiff's failure to warn claims are not preempted.

While Plaintiff may be correct, and the issue is a close one, this Court is bound to follow the Eleventh Circuit law as it remains today.[7] The Medtronic opinion is now six years old, the Papas opinion is now nine years old, yet Papas has not been retreated from nor overruled. The Court notes that several other courts that have considered the issue have found for Defendants. In particular, the California Supreme Court, albeit in a four to three decision, addressed the exact same arguments made by Plaintiff. In its decision, it reviewed case law from many federal circuit courts regarding FIFRA preemption. See Etcheverry v. Tri-Aa Service. Inc., 993 P.2d 306, 373-74 (Cal. 2000). The California Supreme Court concluded that the MDA is distinguishable from the Cigarette Labeling Act and FIFRA because the MDA "gave the FDA a unique role in determining the scope of preemption under the MDA." Id. at 373. The California Court also addressed the argument, supported by an amicus brief by the United States, that the Environmental Protection Agency has specifically disavowed regulated issues of pesticide efficacy, and "concerns itself only with whether a pesticide would have unreasonably adverse effects on human health or the natural environment," but not "whether it will control the target pest or harm the crop it was intended to protect." Id. at 374. The plaintiffs in Etcheverry were suing for crop damage, and not personal injury. Thus, even under the United States' view as presented to the California Supreme Court, personal injury claims for failure

---

[7] Just as the Eighth Circuit was bound to follow its precedent regarding FIFRA preemption in Netland v. Hess and Clark, 284 F.3d 895, 899 (8th Cir. 2002), *cert, filed* August 9, 2002.

to warn would be preempted.[8]

Though Papas preempts failure to warn claims, or any claim based upon labeling or packaging requirement, Papas does not hold that all state law claims are preempted. State tort claims that do not involve labeling or packaging are not preempted. 985 F.2d at 520. Plaintiff may bring claims for strict liability and negligence for design defect or manufacturing defect for manufacture of a product that is unreasonably dangerous, provided that the issue of warning to consumers is not implicated. Plaintiff may not bring an inadequate warning or failure to warn claim under a strict liability or negligence theory. National Bank of Commerce v. Dow, 165 F.3d 602, 608 (8th Cir. 1999).

C. Design Refect Claims

1. Strict Liability

Defendants argue that the issue of warning is implicated in Plaintiffs remaining theories of liability, providing an additional reason for preemption because Florida state law looks to consumer expectations or a risk-benefit test to analyze strict liability claims. See Jennings, 181 F.3d at 1255. Defendants argue that any Florida jury considering strict liability under either test would necessarily need to determine, under an objective test, whether the label or package warnings were reasonable to an ordinary consumer. Id. Though there is no direct Florida state law case discussing FIFRA or similar preemption as to this kind of product liability theory, Defendants do cite to several other jurisdictions, including other federal trial courts, that have agreed with Defendants. See Pages 18-27 of Dow Defendants' Brief in Support of Motion for Summary Judgment [DE 67]. This Court agrees. The Eleventh Circuit in

---

[8] The California Supreme Court rejected the United States' view and concluded that even claims for crop damage based upon a failure to warn theory were preempted.

Jennings states that Florida law requires a jury to consider "the perspective of an 'ordinary consumer' or the 'normal public expectation'" of the danger. 181 F.3d at 1255. The objective expectation of the public regarding the dangerousness of a product necessarily involves consideration of the warning given to the public. Therefore, such design defect claims that Plaintiff brings under Florida law as to Dursban, a product regulated under FIFRA by the federal government, are preempted. But see Jeffers v. Wal-Mart, 171 F.Supp.2d 617, 622-25 (S.D.W.Va. 2001); In re Starlink, 2002 WL 1559667, *4 (N.D.Ill. July 11, 2002).

2. Negligence

With regard to a negligence claim for any design defect, Plaintiff argues that separate from any failure to warn issues, that Defendants could be liable for designing and manufacturing an unreasonably dangerous product, and, because FIFRA does not preempt Florida state law from banning a product outright, Defendants may be liable for tort damage claims. Since FIFRA precludes Plaintiff from bringing a case seeking changes to labeling, the only claim left for Plaintiff to make is that because Florida could ban Dursban outright, a common law claim based upon defective design of an unreasonably dangerous product is not preempted. Such claim, however, suggests that a manufacture would have to not produce Dursban at all to avoid liability (or at least not sell it in Florida), since extra warnings to people such as Plaintiff with chemical sensitivity are not allowed under state law. The Eleventh Circuit statement that "Decisions of the Florida courts demonstrate that a maker or seller of a product need not go to extreme lengths to protect foreseeable users of its products" precludes just such a claim. 181 F.3d at 1257.

D. Manufacturing Defect Claims

Florida law recognizes a strict liability action for a manufacturing defect, in addition to a negligence cause of action. See McCorvey v. Baxter Healthcare Corp., 2002 WL 1669832 (11 th Cir. July 24, 2002); Warren v. K-Mart Corp., 765 So.2d 235, 237 (Fla. 1st DCA 2000) (quoting Restatement (Third) of Torts that "a product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product.") Such claims are not preempted by FIFRA. Nat'l Bank of Commerce, 165 F.3d at 609; Worm v. American Cvnamid Co., 5 F.3d 744, 749 (4th Cir. 1993). Defendants argue that the evidence they have submitted regarding quality control in the Dursban manufacturing process irrefutably rebuts any claim of negligence or strict liability by Plaintiff. See Declaration of Michael Meath, Exhibit B to Dow Defendants' Motion for Summary Judgment [DE 65], This Court agrees. There is no evidence that the Dow product has departed from its intended design.[9]

Though Plaintiff argues in response that he has not had an opportunity to discover facts to support more than an inference of the manufacturing defect claims, Plaintiff has had over nine months to discover such facts. Other than the above one-sentence argument in the conclusion section of his opposition to the Dow Defendants' motion for summary judgment, Plaintiff has not provided sufficient reasons to met the standard of Rule 56(f) of the Federal Rules of Civil Procedure to obtain a continuance of the summary judgment motion. See Nat'l Bank of Commerce, 165 F.3d at 606; Worms, 5 F.3d at 749. Therefore, the Court will grant Defendants' Motion for Summary Judgment in its entirety, on grounds of preemption as to claims for failure to warn and design defect, and as a matter of law that no genuine issue of material fact exists as a manufacturing defect.

---

[9] See below for discussion of Affidavit of Mohamed Bahie Abou-Donia.

E. Motions to Strike

The Court denies Defendants' motion to strike the affidavit of Dr. Mohamed Bahie Abou-Donia, on the grounds that given FIFRA preemption and Florida law as described above, even if everything Dr. Abou-Donia says is true, and the Court must assume so for purposes of a motion for summary judgment, Defendants' motion for summary judgment must be granted. Though Dr. Abou-Donia's affidavit attempts to state that there is a design defect in the Dursban product,[10] there is no duty in Florida to stop selling or manufacturing a product that might be dangerous to a small segment of the population, in the context of a federal regulatory scheme allowing such sale or manufacture and in which the federal scheme forbids states from expanding warning labels approved by the federal government. See above discussion and Jennings v. Bic Corporation, *supra.* Thus, without deciding issues of Daubert admissibility as to Dr. Abou-Donia affidavit, the Court denies the motion to strike his affidavit as moot.

Defendants also moved to strike Plaintiffs affidavit, medical record, answer to interrogatory number 13, and the affidavit of Richard Hosford. Again, the Court concludes that all of this evidences, even if true, does not affect the Court's conclusions made as a matter of law. The motion to strike is therefore denied as moot.

III. CONCLUSION

The motions concerning scheduling and disclosure of experts are decided below. Basically, the Court grants on a *nunc pro tunc* basis Plaintiffs motion for extension of time to

---

[10] See ¶ 14, Affidavit of Mohamed Bahie Abou-Donia, Plaintiffs Notice of Filing, DE 79.

disclose experts. The discovery ruling Plaintiff was waiting for was issued March 25, 2002. The Court has not stricken any experts put forth by Plaintiff. As to Plaintiff's motion for a new scheduling order, the Court will deny this motion. There has been plenty of lime for discovery, even taking into account the discovery motion practice that has occurred.

As to the remaining defendants, the Court notes that Home Depot's Motion for Summary Judgment was just recently filed. As far as the Court can tell from the docket, Defendants Monsanto, Solaris and Scotts have not filed or joined a motion for summary judgment, though the deadline has not yet occurred. Any future such motion should indicate whether those defendants stand in the same position, factually and legally, as the Dow Defendants.

Accordingly, it is **ORDERED AND ADJUDGED** as follows:

1. Dow Defendants' Motion for Summary Judgment [DE 65] is hereby **GRANTED** as to all claims against those Defendants;
2. Plaintiff's Motion for Extension of Time to Disclose Experts [DE 32] is hereby **GRANTED**, *nunc pro tunc* to 30 days after the Scotts Company's response to Judge Johnson's March 25, 2002 Order compelling in part certain discovery;
3. Dow Defendants' Cross Motion to Bar Plaintiff's Use of Undisclosed Expert Testimony [DE 35-2] is hereby **DENIED as moot;**
4. Plaintiff's Motion for Scheduling Conference [DE 42-1] and for New Scheduling Order [DE 42-2] is hereby **DENIED;**
5. Dow Defendants' Cross Motion for Extension of Time of Expert Discovery Deadline [DE 55-2] is hereby **DENIED as moot;**
6. Dow Defendants' Motions to Strike [DE 93 and 96] are hereby **DENIED as moot.**

DONE AND ORDERED in Chambers at Fort Lauderdale, Broward County, Florida, this 26 day of August, 2002.

/S/
WILLIAM P. DIMITROULEAS
United States District Judge

Copies furnished to:
Ian G. Osur, Esq.
Stuart Calwell, Esq.
Douglas J. Chumbley, Esq.
Samuel Danon, Esq.
Daniel J. Gerber, Esq.
James E. Zloch, Esq.
Dean Barnhard, Esq.

(2)

SUPREME COURT, U.S.
FILED
JAN 3 - 2005
OFFICE OF THE CLERK

No. 04-579

IN THE

Supreme Court of the United States

WAYNE CHARLES OKEN,

Petitioner,

v.

THE MONSANTO COMPANY, *et al.*,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF IN OPPOSITION

DEAN T. BARNHARD
Counsel of Record
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, Indiana 46204
(317) 236-1313

Counsel for Respondent
Dow AgroSciences LLC

(*Additional Counsel Listed on Signature Page*)

191839

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

STATEMENT PURSUANT TO RULE 29.6

DowElanco was an Indiana general partnership formed October 31, 1989 between Rofan Services Inc. and Epco, Inc. Rofan Services Inc. is a wholly-owned subsidiary of The Dow Chemical Company ("Dow"). Epco, Inc. was a wholly-owned subsidiary of Eli Lilly and Company, but Epco, Inc. no longer exists. On July 1, 1997, DowElanco became DowElanco LLC, a Delaware limited liability company wholly owned by Dow. On January 1, 1998, DowElanco LLC's name was changed to Dow AgroSciences LLC, which remains a wholly owned subsidiary of Dow.

Scotts Company does not have a parent corporation and no publicly held company owns more than 10% of its stock.

The Monsanto Company involved in the subject litigation is a wholly-owned subsidiary of Pfizer Inc.

Home Depot U.S.A., Inc. does not have a parent corporation and no publicly held company owns more than 10% of its stock.

TABLE OF CONTENTS

Page

Statement Pursuant to Rule 29.6 i

Table of Contents ii

Table of Cited Authorities iv

Statement of the Case 1

Introduction 1

Statement of the Case 6

Reasons for Denying the Petition 11

Oken Withdrew His Lay Evidence, Conceded That His Expert's Affidavit Was Inadmissible, And Admitted He Had "No Evidence Of Toxicity." For These Reasons, Among Others, His Claims, Failed Under State Law For Lack Of Evidence. 11

I. Oken Withdrew His Lay Evidence And His Documentary Submissions. 11

II. Oken Conceded That His Expert's Affidavit Was Inadmissible. 12

III. Oken Has No Evidence Of A Product Defect Or Medical Causation. 13

Contents

Page

IV. Oken Admitted He Had "No Evidence Of Toxicity." 15

V. Overlooking Oken's Fatal Admission Against Interest, His Concession That His Expert's Affidavit Was Inadmissible, And His Withdrawal Of His Lay Evidence, Oken's (Withdrawn) Self-Diagnosis Was Insufficient To Raise A Genuine Issue Of Material Fact As To Medical Causation. 17

VI. Oken's Failure To Offer Evidence Of A Safer, Feasible Alternative Design For The Challenged Products Doomed His Design Defect Claims As A Matter Of State Law. 19

VII. DAS Discharged All Of Its State Law Duties To Oken As A Matter Of Black-Letter Florida Law. The Issue Of FIFRA Preemption As To DAS, Therefore, Need Not Be Reached. 20

Conclusion 22

TABLE OF CITED AUTHORITIES

Page

Cases:

Alexander v. Danek Med., Inc., 37 F. Supp. 2d 1346 (M.D. Fla. 1999) 13

American Int'l Group, Inc. v. Cornerstone Businesses, Inc., 872 So. 2d 333 (Fla. Dist. Ct. App. 2004) 10

Am. Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420 (Tex. 1997) 20

Bates v. Dow AgroSciences LLC, 124 S. Ct. 2903 (2004) (No. 03-388) (oral argument scheduled Jan. 10, 2005) ..... *passim*

Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353 (M.D. Fla. 1999) 3, 13

Bragdon v. Abbott, 524 U.S. 624 (1998) 13

Burton v. United States, 196 U.S. 283 (1905) 3

Cassel v. Price, 396 So. 2d 258 (Fla. Dist. Ct. App.), *review denied*, 407 So. 2d 1102 (Fla. 1981) 19

Cerna v. South Florida Bioavailability Clinic, Inc., 815 So. 2d 652 (Fla. Dist. Ct. App. 2002) 19

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 5

Cited Authorities

	Page
Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993)	13
Drury v. Cardiac Pacemakers, Inc., No. 8:02-CV-933-T-17MAP, 2003 WL 23319650 (M.D. Fla. June 3, 2003)	13
Ferris v. Penn. Federation Brotherhood of Maintenance of Way Employees, 153 F. Supp. 2d 736 (E.D. Pa. 2001)	18
Frank v. Plaza Const. Corp., 186 F. Supp. 2d 420 (S.D.N.Y. 2002)	17
Goewey v. United States, 886 F. Supp. 1268 (D.S.C. 1995), *aff'd*, 106 F.3d 390 (4th Cir. 1997) (mem.), *cert. denied sub nom. Goewey v. Fluor Daniel, Inc.*, 522 U.S. 1045 (1998)	14
Ham v. Lopez, No. Civ. A. SA-01-CA-936-NN, 2002 WL 31396066 (W.D. Tex. Sept. 26, 2002)	18
ISK Biotech Corp. v. Douberly, 640 So. 2d 85 (Fla. Dist. Ct. App. 1994), *review denied*, 651 So. 2d 1194 (Fla. 1995)	6
Jackson v. Berge, 864 F. Supp. 873 (E.D. Wis. 1994)	18
Kayser v. Caspari, 16 F.3d 280 (8th Cir. 1994)	18

Cited Authorities

Page

Kemp v. Metabolife Int'l, Inc., No. 00-3573, 2004 WL 2095618 (E.D. La. Sept. 13, 2004) 17

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) 2

Mobil Oil Corp. v. Bransford, 648 So. 2d 119 (Fla. 1995) 10

Palmas Y Bambu, S.A. v. E. I. DuPont de Nemours & Co., Inc., 881 So. 2d 565 (Fla. Dist. Ct. App. 2004) 6

Pelletier v. Zweifel, 921 F.2d 1465 (11th Cir. 1991) 16

Savage v. Danek Med., Inc., 31 F. Supp. 2d 980 (M.D. Fla.), *aff'd*, 202 F.3d 288 (11th Cir. 1999) 13, 14

Scheman-Gonzalez v. Saber Mfg. Co., 816 So. 2d 1133 (Fla. Dist. Ct. App. 2002) 19

SEC v. Chenery Corp., 318 U.S. 80 (1943) 3

Shell Oil Co. v. Harrison, 425 So. 2d 67 (Fla. Dist. Ct. App. 1982), *review denied*, 436 So. 2d 98 (Fla. 1983) ..... *passim*

Sleath v. West Mont Home Health Servs., Inc., 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow AgroSciences LLC v. Sleath*, 534 U.S. 814 (2001) 5

Cited Authorities

	Page
Smith v. Louisville Ladder Corp., 237 F.3d 515 (5th Cir.), *reh'g en banc denied*, 250 F.3d 745 (5th Cir. 2001)	20
Sprietsma v. Mercury Marine, 537 U.S. 51 (2002)	2
The Monrosa v. Carbon Black Export, Inc., 359 U.S. 180 (1959)	1
Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328 (Tex. 1998)	20
Walker v. Shansky, 28 F.3d 666 (7th Cir. 1994)	18
Word v. Croce, 169 F. Supp. 2d 219 (S.D.N.Y. 2001)	18
Statutes:	
7 U.S.C. §§ 136-136y (Federal Insecticide, Fungicide and Rodenticide Act)	1
7 U.S.C. § 136v(b)	1, 5

Cited Authorities

Page

Rules:

FED. R. CIV. P. 12(b)(6) 2

FED. R. CIV. P. 56(e) 12, 15, 17

FED. R. EVID. 701(c) 12, 15, 17

FED. R. EVID. 702 12

FED. R. EVID. 801(c) 12

FED. R. EVID. 801(d)(2)(A) 15

FED. R. EVID. 801(d)(2)(C) 12

FED. R. EVID. 801(d)(2)(D) 12

FED. R. EVID. 802 12

FED. R. EVID. 803(6) 12

FED. R. EVID. 805 12

Regulations:

40 C.F.R. § 152.130(a) 1

Page

Other Authorities:

Amicus Curiae Brief of the Association of Trial Lawyers of America in Support of Petitioners (filed U.S. No. 03-388) (September 13, 2004) .. 4

RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. (1998) 19

EPA Toxicology Chapter for Chlorpyrifos, April 18, 2000 (*available at* http://www.epa.gov/pesticides/op/chlorpyrifos/rev_tox.pdf) 16

STATEMENT OF THE CASE

Introduction

"While this Court decides questions of public importance, it decides them in the context of meaningful litigation." *The Monrosa v. Carbon Black Export, Inc.*, 359 U.S. 180, 184 (1959). This is not such a case.

Petitioner Wayne Charles Oken ("Oken") is incorrect to argue that because this Court granted *certiorari* review in *Bates v. Dow AgroSciences LLC*, 124 S. Ct. 2903 (2004) (No. 03-388) (oral argument scheduled Jan. 10, 2005), the similarities between the issues upon which he seeks review, and the issues likely to be decided in *Bates*, weigh towards *certiorari* review of his case as well. Oken is correct that both cases involve consideration of the express preemptive effect of 7 U.S.C. § 136v(b), the express preemption clause in the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. §§ 136-136y. Both cases also present questions of implied preemption through conflict with FIFRA's statutory structure, FIFRA's implementing regulatory regime established and enforced by the United States Environmental Protection Agency ("EPA") and, particularly, through conflict with 40 C.F.R. § 152.130(a) ("A registrant may distribute or sell a registered product with the composition, packaging and labeling currently approved by the Agency.").

Oken's case and *Bates* are also substantially similar in that both appear before this Court on fully-developed summary judgment records. *Bates*, therefore, presents at least some claims (although each of them are label-based) that do not involve abstract or hypothetical questions such as those

presented in other recent preemption cases this Court has considered. *E.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (decided on the Illinois state analogue to FED. R. CIV. P. 12(b)(6)); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("[T]he preemption issue was decided on the basis of the pleadings"). Oken's case, however, is much different.

When Respondent Dow AgroSciences LLC ("DAS") moved for summary judgment on the grounds that federal law preempted Oken's personal injury claims, Oken responded with a mountain of lay evidence and unauthenticated documents and one putative expert affidavit, all in an attempt to demonstrate (1) that Oken had indeed suffered a pesticide-related personal injury; and (2) that the two pesticide products accused (DAS's manufacturing grade product sold in bulk and an end-use over-the-counter product that may have incorporated that product) were defective.

When DAS objected to and moved to strike Oken's evidence, Oken agreed that DAS's objections were well-taken, and he voluntarily withdrew all of his documentary evidence and all but an immaterial snippet of his lay affidavit evidence. Oken also voluntarily conceded that his sole expert's affidavit was inadmissible. Oken's withdrawal of his lay evidence and his documentary submissions, and his concession that his expert's affidavit was inadmissible, left him with but one piece of evidence — his own solemn admission against interest that his treating physician diagnosed him as having "no evidence of toxicity."

In short, Oken's voluntary litigation decisions, and his other evidentiary defaults, including his total failure "to provide expert testimony that the product was defective and evidence that the product caused the injury of which [he]

complains," *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999) (citations omitted), left him with no viable state-law claims for federal law to preempt. While the district court based its decision primarily on FIFRA preemption, but did address some of the state-law reasons why Oken's claims necessarily failed, and while the court of appeals affirmed solely on the basis of federal preemption, the fact remains that Oken's own evidentiary failures and his fatal admission against interest conclusively disproved the entirety of his case.

Even if Oken's challenge to FIFRA preemption were to succeed, therefore, it would change nothing as to the correct termination of his individual case. Oken provides no reason why this Court should "disturb the settled rule that, in reviewing the decision of a lower court, it must be affirmed if the result is correct although the lower court relied upon a wrong ground or gave a wrong reason." *SEC v. Chenery Corp.*, 318 U.S. 80, 88 (1943) (citation and internal quotation marks omitted).

Accordingly, Oken's petition should be denied for the straightforward reason that he presents only abstract and hypothetical questions regarding express and implied preemption under FIFRA and its implementing regulatory regime, none of which need be reached. "It is not the habit of this Court to decide questions of a constitutional nature unless absolutely necessary to a decision of the case." *Burton v. United States*, 196 U.S. 283, 295 (1905).

But there is one more important reason why this case is very different from *Bates* and why Oken's petition should be denied. This reason is provided by an unexpected source — the preeminent national plaintiffs' bar association.

In an *amicus* brief filed on September 13, 2004, in support of the Petitioners in *Bates*, the Association of Trial Lawyers of America ("ATLA") identified itself as "a voluntary national bar association whose approximately 50,000 trial lawyer members primarily represent individual plaintiffs in civil actions brought under state tort law." *Amicus Curiae* Brief of the Association of Trial Lawyers of America in Support of Petitioners (filed U.S. No. 03-388) at 1 ("Identity and Interest of *Amicus Curiae*"). In its *amicus* brief, ATLA stated that express preemption of personal injury claims like Oken's was entirely correct, arguing only that a narrow exception to FIFRA preemption should be created for label-based crop damage claims:

> [A]ctions by Congress and the EPA removed property damage claims from the scope of FIFRA preemption. They draw a clear distinction between state claims for personal injury or environmental damage and those for property damage. The former are label-based because the label process requires review and approval of data relating to hazards to humans and the environment.

Id. at 3.

> The effect of these congressional and EPA actions was to carve a small niche out of FIFRA's preemptive scope. . . .
>
> Congress and the EPA have effectively drawn a clear distinction, for preemption purposes, between state claims made for personal injury or environmental damage and those made for property damage. The former are prima facie

> label-based because the label process requires review and approval of data relating to the health of humans and the environment.

Id. at 9-10.

Thus, while Oken's individual counsel argue against FIFRA preemption in the context of personal injury claims, 50,000 of their plaintiffs'-dedicated ATLA colleagues disagree, accepting FIFRA preemption in that context to be a correct application of 7 U.S.C. § 136v(b). Indeed, ATLA and its 50,000 members of the plaintiffs' bar have separately urged this Court to so hold. Respondents here disagree with ATLA's opinion that the preemptive effect of FIFRA § 136v(b)'s plain text tolerates exceptions to it based on any artificial distinction between state law requirements for labeling imposed by label-based property damage claims as contrasted with label-based personal injury claims. Respondents do agree with ATLA's 50,000 plaintiffs' lawyers, however, that if Oken had preserved any state law claims at all, they would be label-based and FIFRA would expressly and impliedly preempt them.

There is, therefore, a significant consensus on the applicability of FIFRA preemption in personal injury cases. This conclusion is punctuated by the fact that Oken points to only one state court decision, and to no federal decision, that has held otherwise since this Court's decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). *See* Pet. at 10 (citing *Sleath v. West Mont Home Health Servs., Inc.*, 16 P.3d 1042 (Mont. 2000), *cert. denied sub nom. Dow AgroSciences LLC v. Sleath*, 534 U.S. 814 (2001)).

It is anomalous, however, for Oken to cling to a Montana state decision as proof of a split in authority meriting *certiorari* review when his home state's courts embrace FIFRA preemption in harmony with the court of appeals here. *See, e.g., Palmas Y Bambu, S.A. v. E. I. DuPont de Nemours & Co., Inc.*, 881 So. 2d 565, 577-79 (Fla. Dist. Ct. App. 2004); *ISK Biotech Corp. v. Douberly*, 640 So. 2d 85, 88 (Fla. Dist. Ct. App. 1994) ("FIFRA preempts all state common law actions that are associated in any way with a claim of inadequate labeling."), *review denied*, 651 So. 2d 1194 (Fla. 1995). Thus, there is no arguable split in authority between Oken's home state courts and the regional federal circuit such as that presented in *Bates*. And, unlike the Petitioners in *Bates*, Oken here makes no argument at all that his case would have been decided differently by Florida's state courts than it was by the courts below. For all these reasons, Oken presents no compelling circumstances requiring *certiorari* review.

STATEMENT OF THE CASE

1. This action arises out of Oken's complaint seeking damages for alleged personal injuries. Oken, who had a history of significant health problems and was pacemaker-dependent, alleged that he purchased two bags of an over-the-counter pesticide, Ortho Dursban Lawn & Garden Insect Control ("Ortho Dursban"), from Respondent Home Depot U.S.A., Inc. ("Home Depot") on October 26, 1996, and he used them on April 13, 1997, to control an infestation of ants in his lawn. Despite the fact that the record directly contradicts his statement, Petitioner argues:

> Shortly thereafter, petitioner began to experience the signs and symptoms of acute cholinergic poisoning. He required immediate hospitalization,

> where he had to be intubated to assist his breathing, and has suffered severe neurological problems since.

Pet. at 2.

Oken's own treating physician, however, rejected Oken's self-diagnosis, concluding, "Insecticide exposure *with no evidence of toxicity.* Adequate cholinesterase levels."

Oken offered his treating physician's conclusion in his evidentiary submission in opposition to DAS's motion for summary judgment and that admission against interest conclusively disproves the entirety of his case. Similarly, there is not a scrap of evidence in the record to support Oken's argument that "he had to be intubated to assist his breathing, and has suffered severe neurological problems since" or that if those problems did exist, they can be causally related to his use of Ortho Dursban as alleged.

2. Dursban® is the registered trademark for a group of insecticides developed, manufactured and marketed by The Dow Chemical Company ("Dow") prior to October 31, 1989, and by DowElanco and then DAS since that date. The active insecticidal ingredient in all Dursban products is chlorpyrifos. DAS sells a variety of technical grade chlorpyrifos products to formulators under various names. Dursban HF Insecticidal Concentrate ("Dursban HF") is one such chlorpyrifos-containing technical grade formulation.

At all material times, Dursban HF was registered with the EPA pursuant to FIFRA. Dow received a stamped and accepted product label from the EPA upon registration of the product. The EPA-accepted Dursban HF label in place

during the pertinent period states that it is "For Manufacturing Use Only" and that:

> Because of their properties and intended uses, insecticidal formulations containing DURSBAN HF insecticide will require precautionary labeling differing from that given. Formulators should develop their own use and precautionary labeling, based on the properties and intended uses of their own finished formulations, and are responsible for obtaining EPA registration of these products. [1]

The Dursban HF label also provides:

WARNING

* * *

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

MAY BE FATAL IF SWALLOWED • EXCESSIVE ABSORPTION THROUGH SKIN MAY BE FATAL • CAUSES EYE IRRITATION • MAY CAUSE SKIN IRRITATION

* * *

---

1. This label language is particularly important because it operates to discharge all of DAS's Florida state law duties to Oken as a matter of black-letter Florida law. *Shell Oil Co. v. Harrison*, 425 So. 2d 67 (Fla. Dist. Ct. App. 1982), *review denied*, 436 So. 2d 98 (Fla. 1983). *See* Section VII.

STATEMENT OF PRACTICAL TREATMENT:

* * *

NOTE TO PHYSICIAN: Chlorpyrifos is a cholinesterase inhibitor. Treat symptomatically. If exposed, plasma and red blood cell cholinesterase tests may indicate significance of exposure (baseline data are useful).

DAS observes strict quality assurance manufacturing protocols to assure that each production batch of technical grade chlorpyrifos and Dursban HF is in compliance with DAS's production specifications, the EPA-approved confidential statements of formula, and EPA's regulations governing product quality and consistency.[2] At all times relevant hereto, DAS has always sold Dursban HF with EPA-accepted labels affixed to the product's containers at the time of the sale, and has sold it only in bulk to formulators such as The Solaris Group ("Solaris"), formerly a division of the Agricultural Group of Respondent the Monsanto Company ("Monsanto"). Oken does not dispute these facts.

3. Solaris originally registered Ortho Dursban as "Ortho-Klor 1% Dursban Lawn & Soil Granules" under EPA registration number 239-2570. Solaris notified EPA per PR Notice 95-2 of the assumed business name for this product, "Ortho Dursban Lawn & Garden Insect Control," on January 10, 1996. Monsanto at all times sold Ortho Dursban with the EPA-approved label affixed to the product at the time of sale. (The Ortho Dursban label is reproduced in an appendix

---

2. Indeed, Oken has voluntarily abandoned any claim that any of the accused products here had a manufacturing defect.

to the court of appeals' opinion. *See* Pet. App. at 5a-8a.) Dursban HF and Ortho Dursban were also registered by the Florida Department of Agriculture and Consumer Services pursuant to the Florida Pesticide Law. Oken does not dispute these facts.

Neither DAS nor its predecessors designed, made or sold "Ortho-Klor 1% Dursban Lawn & Soil Granules" or Ortho Dursban. Dursban HF, however, may have been used as an active ingredient in Ortho Dursban. Oken argues that "Dow and Monsanto were both integral participants in the design and marketing of Ortho Dursban Lawn & Garden Insect Control." Pet. at 3. There is not a scrap of evidence in the record (or outside of it), however, to support this factually-incorrect argument.[3]

4. Sometime between November 11, 1998 and January 21, 1999, Respondent the Scotts Company ("Scotts") acquired from Monsanto the assets of the Ortho product line,

---

3. It is immaterial that DAS may have authorized Monsanto to use the Dursban trademark in connection with its end-use product. *See Harrison*, 425 So. 2d 67 (reversing verdict against bulk supplier of pesticide active ingredient to end-use product formulator despite bulk supplier's authorization to end-use formulator to use bulk supplier's trademark on label of end-use product). *See also, e.g.*, *Mobil Oil Corp. v. Bransford*, 648 So. 2d 119, 120 (Fla. 1995) ("In today's world, it is well understood that the mere use of franchise logos and related advertisements does not necessarily indicate that the franchisor has actual or apparent control over any substantial aspect of the franchisee's business. . . ."); *American Int'l Group, Inc. v. Cornerstone Businesses, Inc.*, 872 So. 2d 333, 336 (Fla. Dist. Ct. App. 2004) ("Florida law is clear that the use of a logo or trademark symbol alone cannot create an apparent agency.") (citations omitted).

which included Ortho Dursban. Because Scotts did not acquire the Ortho product line from Monsanto until January, 1999, it could not have designed, manufactured or sold the specific Ortho Dursban Oken allegedly purchased in October of 1996. Oken does not dispute these facts and he has never articulated any reason why Scotts could be liable to him; yet, he stubbornly refuses to voluntarily dismiss Scotts from these proceedings. Respondent Home Depot was a mere retailer of the Ortho Dursban and had no responsibility for the manufacture, packaging or labeling of that product.

REASONS FOR DENYING THE PETITION

The petition should be denied for the straightforward reason that all of Oken's claims failed under state law. The fact that the lower courts did not reach these state law reasons provides no basis for this Court to reach Oken's hypothetical and abstract arguments against federal preemption.

OKEN WITHDREW HIS LAY EVIDENCE, CONCEDED THAT HIS EXPERT'S AFFIDAVIT WAS INADMISSIBLE, AND ADMITTED HE HAD "NO EVIDENCE OF TOXICITY." FOR THESE REASONS, AMONG OTHERS, HIS CLAIMS, FAILED UNDER STATE LAW FOR LACK OF EVIDENCE.

I. Oken Withdrew His Lay Evidence And His Documentary Submissions.

Oken opposed DAS' motion for summary judgment by offering his own and his domestic partner Richard Hosford's affidavits, his answers to Epco, Inc.'s interrogatories, and a jumble of unauthenticated medical records. DAS properly objected because the affidavits and interrogatory answers

were rife with multiple layers of hearsay (FED. R. EVID. 801(c); 802; 805), were pregnant with inadmissible lay opinions (FED. R. EVID. 701(c); FED. R. CIV. P. 56(e)), and there was no foundation for the records or the hearsay and opinions within them (FED. R. EVID. 802; 803(6); 805; 702), among other objections.

Oken conceded that DAS made "reasonably sound objections" and affirmatively *withdrew* his offered evidence.[4] Oken's voluntary withdrawal of this proffered material left him without evidence to suggest that he suffered any harm. The same is true as to Oken's sole "expert" affidavit.

II. Oken Conceded That His Expert's Affidavit Was Inadmissible.

Oken understood that Florida law required him to oppose DAS's motion for summary judgment with expert evidence demonstrating (1) product defect and (2) medical causation. *See* Section III. To meet these required elements, Oken offered one putative "expert" affidavit in response to DAS' motion for summary judgment. When DAS objected and moved to strike it, Oken conceded its inadmissibility: "Dow correctly notes that Dr. Abou-Donia's Affidavit lacks

4. The sole exception Oken sought to preserve was his affidavit testimony "that the [Home Depot] 'sales person . . . said I did not need to wear gloves or a mask, just that I should read the label."' This alleged statement by an unidentified Home Depot employee was hearsay and unavailable as evidence against DAS, Monsanto or Scotts. *See* FED. R. EVID. 801(d)(2)(C)&(D). As to Home Depot, this testimony is irrelevant because Oken admitted that his sole expert's affidavit was inadmissible and, therefore, he had no evidence to demonstrate that the Ortho Dursban product label was itself defective or inadequate. *See* Sections II and III.

information that would be necessary to evaluate his testimony under the standards of Rule 702 and Daubert.[5] " *See Bragdon v. Abbott*, 524 U.S. 624, 653 (1998) ("Scientific evidence and expert testimony must have a traceable, analytical basis in objective fact before it may be considered on summary judgment.") (citation omitted).

Because Oken agreed that Dr. Abou-Donia's Affidavit was inadmissible, he was left with no expert evidence of any kind, a fatal defect under settled Florida state law.

III. Oken Has No Evidence Of A Product Defect Or Medical Causation.

Oken presented no competent expert testimony to support the existence of any defect claim of any kind, preempted or not. "[A] defect must be proven by expert testimony." *Alexander v. Danek Med., Inc.*, 37 F. Supp. 2d 1346, 1349 (M.D. Fla. 1999); *Savage v. Danek Med., Inc.*, 31 F. Supp. 2d 980, 983 (M.D. Fla.) (same), *aff'd*, 202 F.3d 288 (11th Cir. 1999) (mem.); *Blinn v. Smith & Nephew Richards, Inc.*, 55 F. Supp. 2d 1353, 1360 (M.D. Fla. 1999) ("Plaintiff [is] required to provide expert testimony that the product was defective and evidence that the product caused the injury of which [he] complains."); *Drury v. Cardiac Pacemakers, Inc.*, No. 8:02-CV-933-T-17MAP, 2003 WL 23319650, at *4 (M.D. Fla. June 3, 2003) ("Design defects must be proven by expert testimony.").

Oken's inadmissibility concession aside, it is uncontested that Dr. Abou-Donia is not a medical doctor, he never examined Oken, and he never pretended to offer an opinion

---

5. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

that Oken's use of Ortho Dursban in fact caused Oken's injuries. All that aside, Dr. Abou-Donia's Affidavit was not competent to demonstrate a product defect or medical causation, general or specific:

> Dr. Abou-Donia is a research scientist who is engaged in research on adult chickens in order to study the delayed onset (OPIDN) [organophosphate induced delayed neuropathy] of the neurotoxic effects of TOCP [tri-ortho-cresyl phosphate] exposure. He does no work on humans, and performs strictly laboratory research.
>
> * * *
>
> Dr. Abou-Donia's conclusions are extrapolated from his work on chickens [and] ... cannot meet the threshold test of reliability under *Daubert* and therefore, may not be considered probative of causation.

Goewey v. United States, 886 F. Supp. 1268, 1280-81 (D.S.C. 1995), *aff'd*, 106 F.3d 390 (4th Cir. 1997) (mem.), *cert. denied sub nom. Goewey v. Fluor Daniel, Inc.*, 522 U.S. 1045 (1998).[6]

Because Oken conceded that his expert's testimony was inadmissible, all his claims failed as a matter of settled Florida state law. Thus, summary judgment was proper, federal preemption aside.

---

6. "The Court need not reach the issue of causation because [Oken] failed to show any evidence that [he] can use to prove the [product] is defective." *Savage*, 31 F. Supp. 2d at 984 (citations omitted).

IV. Oken Admitted He Had "No Evidence Of Toxicity."

Oken's interrogatory answers offered in opposition to DAS's motion for summary judgment contained a fatal admission against interest. Oken quoted his treating physician's diagnosis as follows:

> Wayne was discharged with the following conclusions . . . . ***"Insecticide exposure with no evidence of toxicity. Adequate cholinesterase levels."***

While objecting to and moving to strike the remainder of Oken's offer of his interrogatory answers, DAS cross-moved for admission of this highlighted text as an admission of a party-opponent under FED. R. EVID. 801(d)(2)(A). Oken did not object to DAS's sponsorship of his admission against interest, nor did he attempt to withdraw it. Oken's solemn admission against interest, therefore, is firmly planted in the evidentiary record.[7]

Oken's factual admission that he had "[a]dequate cholinesterase levels" and "no evidence of toxicity" conclusively disproved any notion that he experienced any chlorpyrifos-related injury. The Dursban HF label prominently states:

> **NOTE TO PHYSICIAN**: Chlorpyrifos is a cholinesterase inhibitor. Treat symptomatically.

---

7. In the balance of Oken's response to this interrogatory, he tried to explain away his treating physician's dispositive conclusion by making arguments that he was not competent or qualified to make. *See* FED. R. EVID. 701(c); FED. R. CIV. P. 56(e).

> If exposed, plasma and red blood cell cholinesterase tests may indicate significance of exposure (baseline data are useful).

As EPA recently explained:

> Chlorpyrifos affects the nervous system by reversibly inhibiting the activity of cholinesterase (ChE), an enzyme necessary for the proper functioning of the nervous system. Inhibition of ChE is the most sensitive effect in . . . humans, regardless of exposure duration.

EPA Toxicology Chapter for Chlorpyrifos, April 18, 2000, p. 2 (*available at* http://www.epa.gov/pesticides/op/chlorpyrifos/rev_tox.pdf).

Oken's admission that he had "no evidence of toxicity" and "[a]dequate cholinesterase levels" conclusively proved the opposite of his allegations. *E.g.*, *Pelletier v. Zweifel*, 921 F.2d 1465, 1507 (11th Cir. 1991) ("[W]hen the plaintiff's evidence conclusively proves the opposite of his allegations, summary judgment in the defendant's favor is appropriate."). Summary judgment, therefore, was appropriate, federal preemption notwithstanding.

V. Overlooking Oken's Fatal Admission Against Interest, His Concession That His Expert's Affidavit Was Inadmissible, And His Withdrawal Of His Lay Evidence, Oken's (Withdrawn) Self-Diagnosis Was Insufficient To Raise A Genuine Issue Of Material Fact As To Medical Causation.

Overlooking Oken's fatal admission against interest, his concession that his sole expert's affidavit was inadmissible, and his withdrawal of his lay and documentary evidence, Oken's (withdrawn) self-diagnosis was insufficient to raise a genuine issue of material fact. The competency requirements of FED. R. CIV. P. 56(e), and the evidentiary requirements of FED. R. EVID. 701(c) (as amended in 2000), forbade consideration of Oken's self-diagnosis on summary judgment. The law here is well-settled. *See, e.g., Kemp v. Metabolife Int'l, Inc.*, No. 00-3513, 2004 WL 2095618, at *6 (E.D. La. Sept. 13, 2004) ("Courtney is not a doctor, and therefore, as with the other Plaintiffs, she is not qualified to provide medical evidence of causation.").

> To the extent that [Plaintiffs' affidavit testimony] is a repetition of a diagnosis given her by a qualified professional, it is hearsay. To the extent it is her own opinion, there has been no showing that she is qualified to make the diagnosis . . . .

Frank v. Plaza Const. Corp, 186 F. Supp. 2d 420, 433 (S.D.N.Y. 2002) (footnotes omitted).

> If Ham's conclusions as stated in his Affidavit are based on his own self-diagnosis, then they are incompetent because there is no showing he is an expert[.] . . . [O]n the otherhand [sic], if these

> conclusions are based on what he was told by others then these statements are incompetent hearsay. Affidavits, such as this . . . are not competent summary judgment evidence.

Ham v. Lopez, No. Civ. A. SA-01-CA-936-NN, 2002 WL 31396066, at *5 (W.D. Tex. Sept. 26, 2002) (citations omitted). *See also Word v. Croce*, 169 F. Supp. 2d 219, 226 (S.D.N.Y. 2001) ("Plaintiff's self-diagnosis of irritable bowel syndrome is insufficient to support a medical condition requiring a special diet."); *Ferris v. Penn. Federation Brotherhood of Maintenance of Way Employees*, 153 F. Supp. 2d 736, 746 (E.D. Pa. 2001) ("Ferris's beliefs as to how his injuries were caused may not be presented to the jury in the absence of expert testimony regarding causation. . . ."); *Walker v. Shansky*, 28 F.3d 666, 672 (7th Cir. 1994) ("Walker's self-serving conclusions about his mental health are insufficient to withstand the defendants' motion for summary judgment. . . . [T]here is no evidence that Walker is qualified to testify as to his medical condition."); *Jackson v. Berge*, 864 F. Supp. 873, 881 (E.D. Wis. 1994) (Plaintiff "claims to have asthma and to suffer from chest pains, but he has produced no expert opinion or other competent evidence to support this self-diagnosis."); *Kayser v. Caspari*, 16 F.3d 280, 281 (8th Cir. 1994) ("Kayser's self-diagnosis alone cannot establish that he does, in fact, suffer from kidney stones. . . .").

Thus, even if Oken had not withdrawn his lay and documentary evidence, his self-diagnosis was entirely insufficient to raise a genuine issue of material fact that he suffered any injury caused by the accused products.

Similarly, Oken's self-reported symptoms allegedly occurring shortly after he used the Ortho Dursban proves nothing under Florida law. "[T]emporal proximity alone does not prove causation." *Cerna v. South Florida Bioavailability Clinic, Inc.*, 815 So. 2d 652, 656 (Fla. Dist. Ct. App. 2002). Moreover, under Florida law, "the mere occurrence of an accident does not give rise to an inference of negligence, and is not sufficient for a finding of negligence on the part of anyone." *Cassel v. Price*, 396 So. 2d 258, 264 (Fla. Dist. Ct. App.) (citations omitted), *review denied*, 407 So. 2d 1102 (Fla. 1981). Accordingly, there is not a scrap of admissible evidence to support any of Oken's claims.

VI. Oken's Failure To Offer Evidence Of A Safer, Feasible Alternative Design For The Challenged Products Doomed His Design Defect Claims As A Matter Of State Law.

Florida law requires that to make a *prima facie* case of design defect, a plaintiff must offer proof of a safer, feasible alternative design for the accused product. *See Scheman-Gonzalez v. Saber Mfg. Co.*, 816 So. 2d 1133, 1139 (Fla. Dist. Ct. App. 2002) ("[A] product is defective in design 'when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design' and its omission 'renders the product not reasonably safe.'") (quoting RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(b) (1998)). *See id.* at § 2 cmt. f ("To establish a *prima facie* case of defect, the plaintiff must prove the availability of a technologically feasible and practical alternative design that would have reduced or prevented the plaintiff's harm.").

Oken has never argued nor offered a scrap of evidence that there is a safer, feasible alternative design for the molecular structure of chlorpyrifos, for the formulation of Dursban HF, or for the formulation of Ortho Dursban. That fatal evidentiary default is yet another reason why his putative design defect claims failed as a matter of Florida state law.[8]

VII. DAS Discharged All Of Its State Law Duties To Oken As A Matter Of Black-Letter Florida Law. The Issue Of FIFRA Preemption As To DAS, Therefore, Need Not Be Reached.

In *Shell Oil Co. v. Harrison*, 425 So. 2d 67 (Fla. Dist. Ct. App. 1982), *review denied*, 436 So. 2d 98 (Fla. 1983), Shell was (like DAS is here) a manufacturer and bulk supplier of an active ingredient used by other formulators in the production and sale of over-the-counter pesticides; in that case, soil fumigants. Shell's product and its label (like Dursban HF and its label) were regulated by the EPA under FIFRA. 425 So. 2d at 68.

---

8. This is another point of substantial similarity with *Bates*. There, Texas state law, like Florida state law, requires competent proof of a safer, feasible alternative design to make a *prima facie* case of design defect, negligent design, or breach of implied warranty. *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997). *See also id.* at 433 n.9; *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 335 n.4 (Tex. 1998); *Smith v. Louisville Ladder Corp.*, 237 F.3d 515, 521 (5th Cir.) ("[B]ecause Smith failed to establish a safer alternative design for the ladder in use at the time of the accident, his claim predicated on breach of implied warranty must fail, along with his design defect claim."), *reh'g en banc denied*, 250 F.3d 745 (5th Cir. 2001). Petitioners in *Bates*, like *Oken* here, offered no such evidence.

A container of an over-the-counter product containing Shell's active ingredient, purchased from a lawn and garden shop, fell from the shelf where it was stored, shattered, and plaintiff was injured in his efforts to clean up the spill. *Id.* at 69. Plaintiff sued "alleging negligence, strict liability and breach of an implied warranty by Shell. . . ." *Id.* at 68. The court of appeal reversed plaintiff's jury award rejecting, first, the notion that a "manufacturer and bulk supplier of a dangerous toxic component [has] a nondelegable duty to warn ultimate users of the hazards of commodities containing the toxic component when the commodities were formulated, packaged, labeled, and distributed by others[.]" *Id.* at 70. In a holding directly on point, the court then said:

> The federal regulatory system provides for EPA approval and oversight of the labeling and packaging of chemical formulations prepared for sale to the public. These labeling and packaging requirements necessarily differ depending upon the particular formulation and, thus, place the responsibility on the formulator for providing adequate warning to the public and for obtaining EPA approval. ***Shell, as the manufacturer or supplier selling in bulk to one other than an ultimate consumer, took the necessary precautions commensurate with the dangers reasonably anticipated under the circumstances.***

Id. (emphasis added).

DAS's EPA-approved Dursban HF label, exactly like the EPA-approved label described in *Shell*, "place[s] responsibility on the formulator for providing adequate warning to the public and for obtaining EPA approval."

See p. 8. Thus, "[DAS], as the manufacturer or supplier selling in bulk to one other than an ultimate consumer, took the necessary precautions commensurate with the dangers reasonably anticipated under the circumstances." 425 So. 2d at 70. Accordingly, DAS discharged all of its state law duties to Oken as a matter of black-letter Florida law and the issue of FIFRA preemption, as to DAS, need not be reached.

CONCLUSION

The petition should be denied because it presents only abstract, hypothetical and theoretical questions regarding federal preemption. Oken's entirely voluntary withdrawal of his lay and documentary evidence, his concession that his sole expert's affidavit was inadmissible, and his admission against interest that he had "no evidence of toxicity" left him with no case for federal law to preempt.

Respectfully submitted,

DEAN T. BARNHARD
Counsel of Record
BARNES & THORNBURG LLP
11 South Meridian Street
Indianapolis, Indiana 46204
(317) 236-1313

Attorneys for Respondent
Dow AgroSciences LLC

SAMUEL A. DANON, ESQUIRE
HUNTON & WILLIAMS
BARCLAY'S FINANCIAL CENTER
1111 Brickell Avenue, Suite 2500
Miami, Florida 33131

Counsel for Scotts Company

LAWRENCE E. MARGOLIS, ESQUIRE
DANIELS, KASHTAN, DOWNS,
ROBERTSON & MAGATHAN
3300 Ponce De Leon Boulevard
Miami, Florida 33134

Counsel for Home Depot U.S.A., Inc.

WENDY F. LUMISH, ESQUIRE
CARLTON FIELDS, P.A.
4000 BANK OF AMERICA TOWER
@ INTERNATIONAL PLACE
100 Southeast Second Street
Miami, Florida 33131

Counsel for Monsanto Company

No. 04-579

In The Supreme Court of the United States

Supreme Court
FILED
FEB 8 - 2
OFFICE OF THE CLERK

WAYNE CHARLES OKEN,

Petitioner,

v.

THE MONSANTO COMPANY, *et al.*,

Respondents.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

REPLY TO BRIEF IN OPPOSITION

Stuart Calwell
Counsel of Record
THE CALWELL PRACTICE
Law and Arts Center West
500 Randolph Street
Charleston, West Virginia 25302
(304) 343-4323

Alex McLaughlin
THE CALWELL PRACTICE
178 Chancery Row
Morgantown, West Virginia 26505
(304) 291-5223

Counsel for Petitioners

THE LEX GROUP ♦ 1108 East Main Street ♦ Suite 1400 ♦ Richmond, VA 23219
(804) 644-4419 ♦ (800) 856-4419 ♦ Fax: (804) 644-3660 ♦ www.thelexgroup.com

TABLE OF CONTENTS

PAGE

TABLE OF CONTENTS i

TABLE OF AUTHORITIES ii

I. Introduction 1

II. Respondents' Opposition to Certiorari Does Not Undermine the Reasons for Granting the Petition 2

A. Respondents' Procedural Reasons for Denying the Petition Lack Merit 3

B. Personal Injury Claims and Crop Injury Claims Are Not Distinguishable for Purposes of FIFRA Preemption 5

III. Conclusion 10

TABLE OF AUTHORITIES

PAGE(S)

CASES:

Bates v. Dow AgroSciences LLC,
124 S. Ct. 2903 (2004) 6, 7, 9

Celotex Corp. v. Catrett,
477 U.S. 317 (1986) 4

Cipollone v. Ligget Group, Inc.,
505 U.S. 504 (1992) 7

Medtronic, Inc. v. Lohr,
518 U.S. 470 (1996) 6, 7, 8

Wisconsin Public Intervenor v. Mortier,
501 U.S. 597 (1991) 1

Worm v. American Cyanamid Co.,
5 F.3d 744 (4th Cir. 1993) 1

STATUTES:

7 U.S.C. §§ 136-136y ..... *passim*

7 U.S.C. § 136v 9

7 U.S.C. § 136v(a) 1, 8, 9

7 U.S.C. § 136v(b) 1, 7, 8, 9

21 U.S.C. § 360k 7

21 U.S.C. § 360k(a) 7

I. *Introduction*

Respondents' opposition to certiorari does not address the most compelling reason that this Court should grant the petition: Although a clear majority of lower courts agree that section 136v(b) of the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. §§ 136-136y ("FIFRA"), preempts "label-based" personal injury claims against the manufacturers of registered pesticides, those courts are confused and divided about how they should scrutinize state-law design defect claims to determine whether those claims fall within that preemptive reach.

The petition explains (at 6–15) that the Eleventh Circuit's "forbidden inquiry" analysis and its holding in this case are at odds with the reasoning and analysis of those lower courts that follow the Fourth Circuit's analysis in *Worm v. American Cyanamid Co.*, 5 F.3d 744, 747–48 (4th Cir. 1993), which holds that preemption of design defect claims turns on "whether one could reasonably foresee that the manufacturer, in seeking to avoid liability for the error, would choose to alter the product or the label." The petition also explains (at 15–16) that the Eleventh Circuit's forbidden inquiry analysis—under which states are not free even *to consider*, in going about their regulatory affairs, the adequacy of a pesticide label that has been approved by the United States Environmental Protection Agency ("EPA")—conflicts with this Court's prior holding that FIFRA section 136v(a) serves to prevent states from being preempted out of the field of pesticide regulation altogether through apparent or actual conflicts. *See Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 607 (1991) (explaining that section 136v(a) "acts to ensure that the States could continue to regulate use and sales even where, such as with regard to the banning of mislabeled products, a narrow preemptive overlap might occur").

The petition points out (at 9, 12-14) that this case is ideally suited for clarifying the confusion among the lower courts concerning FIFRA preemption because the applicable state product liability law and the factual allegations in the case squarely present the issue that has proved most vexatious to the lower courts. Under Florida law, a design defect claim can be proved either by (1) satisfying a risk-utility test, in which the adequacy of the labeling is one factor among many, or (2) satisfying a test premised on consumer expectations. Petitioner alleges that the active ingredient of a do-it-yourself lawn and garden pesticide is too dangerous to be used around residences or handled by non-professionals. This is precisely the sort of claim—a claim in which the label's substance and adequacy are relevant under state law even though the allegation is that the product's composition (in this case, the active ingredient) should have been changed—that causes so much confusion in the lower courts.

II. *Respondents' Opposition to Certiorari Does Not Undermine the Reasons for Granting the Petition*

Strikingly, Respondents' opposition to certiorari does not quarrel with any of the main points raised in the petition. Instead, Respondents present two arguments that can be described, charitably, as creative. Respondents dedicate the entire "Reasons for Denying the Petition" section of their opposition brief to an exhaustive review of evidence that was voluntarily withdrawn, although they fail to mention that it was withdrawn because it did not need to be submitted in the first instance. The only attention that the opposition pays to FIFRA preemption is in the introduction, where one discovers that "50,000 member of the plaintiffs' bar" have "urged" this Court to adopt a position on FIFRA preemption that completely prohibits personal injury actions against pesticide manufacturers (Br. in Opp. 5).

A. Respondents' Procedural Reasons for Denying the Petition Lack Merit

Respondents do not quarrel with the petition's statement of the case or the characterization of the allegations in the proceedings below. Respondents do not dispute that the thrust of Petitioner's allegations is that the active ingredient of Ortho Dursban Lawn & Garden Insect Control is too dangerous to be used by nonprofessionals and around residences; nor do they dispute that Petitioner insisted in the proceedings below that these allegations, if generally accepted as true, would cause a reasonable manufacturer to change his product (by substituting a different active ingredient) rather than the label. Instead, Respondents dedicate almost their entire brief in opposition to making much of the fact that Petitioner "voluntarily withdrew" (Br. in Opp. 2) and "affirmatively withdrew" (Br. in Opp. 12) documentary evidence and conceded the inadmissibility of an expert affidavit.

Although Respondents appear to believe that Petitioner should be especially ashamed of himself for having *voluntarily withdrawn* evidence in response to the objections of Respondent Dow AgroSciences in the proceedings in the district court, fear of losing another motion (in addition to the potentially dispositive summary judgment motion) is not the only possible explanation for this behavior, or even a sensible one. The real explanation can be found right at the outset of the opposition brief itself: "When Respondent Dow AgroSciences moved for summary judgment *on the grounds that federal law preempted [Petitioner's] personal injury claims,* [Petitioner] responded with . . . lay evidence and unauthenticated documents and one putative expert affidavit" (Br. in Opp. 2). Neither Respondent Dow AgroSciences initially, nor any Respondent subsequently, so much as hinted in a summary judgment motion that absence of a genuine issue of material

fact on causation or design defect[1] was a basis for the motion.

There was, therefore, no obligation at any point in the proceedings for Petitioner to come forth with evidence on causation or design defect. "Of course, a party seeking summary judgment always bears the initial responsibility of informing the district court of the basis for its motion." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Even for issues on which the nonmoving party bears the burden, the moving party must at least go to the trouble of "pointing out to the district court . . . that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325.

Neither Dow AgroSciences nor anyone else ever triggered a duty to produce evidence on causation or design defect. It is this fact, not fear of losing a much less significant motion, that explains why Petitioner chose not to litigate the admissibility of evidence that was hastily and unnecessarily produced in the first place and *voluntarily withdrew* it instead. Dow AgroSciences first made this argument—that the preemption issue is moot because Petitioner did not introduce evidence on causation and design defect in response to its summary judgment motion—to the court of appeals. Dow AgroSciences and the other Respondents are free to make the argument again on remand. It received zero attention from the panel the first time, and it is therefore undeserving of this Court's attention now. The court of appeals based its decision exclusively on FIFRA preemption, and that decision and that issue are important and are worthy of this Court's attention.

---

[1] Absence of evidence of manufacturing defect and negligent manufacturing was a basis of the Dow defendants' original summary judgment motion, but that was the only factual basis of any summary judgment motion.

Contrary to Respondents' claim, this case is ready to be resolved by this Court "on the basis of the pleadings" and the existing record (Br. in Opp. 1–2). Respondents do not contest that the allegations and arguments set forth in the petition were stated below. The case comes to this Court with these allegations: Chlorpyrifos is an active ingredient contained in Dursban HF. Dursban HF was used in the formulation of Ortho Dursban Lawn & Garden Insect Control. Petitioner alleges that chlorpyrifos is too dangerous for use by nonprofessionals and use around residences. Dursban HF is also used in products that are used under professional supervision on agricultural and other nonresidential sites; Ortho Dursban Lawn & Garden Insect Control is a do-it-yourself lawn and garden pesticide. Perhaps the claim that Dursban HF is defective is inescapably an attack on the label, but even the emerging consensus among lower courts that label-based claims are preempted is important enough to warrant this Court's scrutiny. The allegation of a design defect in Ortho Dursban Lawn & Garden Insect Control, on the other hand, is not the kind that can be remedied by changing the label; it can only be remedied by changing the product's active ingredient. As the petition explained (at 14–15), and the Respondents do not challenge in their brief in opposition, the lower courts disagree on whether such a claim is preempted because of ancillary questions that a jury may be called upon to consider in the course its deliberations. The issues are well framed and ready for resolution.

B. Personal Injury Claims and Crop Injury Claims Are Not Distinguishable for Purposes of FIFRA Preemption

The Respondents' opposition to certiorari does not address the confusion among the lower courts concerning the status of certain kinds of design defect claims. The closest Respondents come to addressing this or any issue related to FIFRA preemption is in the introduction to their

brief in opposition, where Respondents sidestep the courts altogether, ignore the framing of the issue in the petition, and boldly proclaim that a consensus has been reached between pesticide manufacturers, on the one hand, and 50,000 plaintiffs lawyers on the other (Br. in Opp. 4–6). This consensus, evidenced by an *amicus* brief filed on behalf of the Association of Trial Lawyers of America ("ATLA") (and so naturally its 50,000 members) in a case now before this Court involving claims for crop damage, is that all personal injury claims against pesticide manufacturers are "label-based" because of EPA's label review process and, therefore, preempted (Br. in Opp. 4–5). Petitioner is thereby cast as an outlier or worse, given that Petitioner's counsel of record is himself a member of the Association of Trial Lawyers of America, a dissident.

Setting aside some of the statements in the opposition to certiorari regarding ATLA's *amicus* brief that are clearly over the top—whether the authors of the ATLA brief really conceded that FIFRA preempts most personal injury claims or merely assumed it for the purpose of an argument about crop damage is debatable, but even the authors of the *amicus* brief plainly did not "urge this Court to so hold," and to suggest that ATLA's "50,000 members of the plaintiffs' bar" have also "urged this Court to so hold" borders on the absurd (Br. in Opp. 5)—the authors of ATLA's *amicus* brief in support of certiorari in *Bates v. Dow AgroSciences LLC*, 124 S. Ct. 2903 (2004), do base their support of the *Bates* petition on a clear distinction between FIFRA preemption of crop injury claims and FIFRA preemption of personal injury claims. The ATLA authors reason that because EPA does not regulate efficacy, which includes harm to target crops, this Court will follow its holding in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (*"Medtronic"*) and hold that the claims not preempted. *See Amicus Curiae* Brief of the Association of Trial Lawyers of

America in Support of Petitioners (filed U.S. No. 03-388) at 20 (September 13, 2004).

Respondents' reliance on ATLA's position in *Bates* may be intended to suggest that ATLA's argument—that there is a clear difference for preemption purposes between crop injury claims and personal injury claims—is so *patently obvious* that there is no reason for this Court to "hold" this case, a personal injury case, and remand it to the Eleventh Circuit for reconsideration in light of *Bates*, a crop injury case. However, ATLA's argument that FIFRA preemption turns on whether EPA actually reviews data that covers the aspect of the pesticide's labeling that is suspect is not only *not obvious*, it is *completely unsupported* by the language of FIFRA and this Court's holding in *Medtronic*. The reasoning of ATLA's *amicus* brief attempts to trace *Medtronic*: "Under the similar preemption provision in the Medical Device Amendments"—the alleged similarity is more than a little suspect—"'a state law will be preempted only to the extent that the FDA has established a relevant federal 'requirement.'" *Id.* (*quoting Medtronic*, 518 U.S. at 496). ATLA rather astutely omitted an important part of the passage from *Medtronic* preceding the part it quoted, which reads: "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect. Unlike the statute construed in *Cipollone* [*v. Ligget Group, Inc.*, 505 U.S. 504 (1992)], for instance, pre-emption under the MDA does not arise directly as a result of the enactment of the statute." *Medtronic*, 518 U.S. at 495–96.

The preemption provision in MDA section 360k(a) is different in critical ways from FIFRA section 136v(b), most notably in its dependence on the issuance of a device-specific requirement from FDA for any actual preemption of state-imposed requirements to occur. *See Medtronic*, 518 U.S. at 498. In contrast, FIFRA section 136v(b) preempts "any requirements for labeling or packaging in addition to or

different from those required under this subchapter." In other words, FIFRA commands the EPA to regulate and establish requirements for the labeling of all pesticides, and states are absolutely forbidden from issuing any commands for labeling of their own, regardless of what the EPA has or has not considered in establishing the federal labeling requirements, regardless of whether Congress has exempted the EPA from stringent pre-approval review of certain kinds of data in establishing those requirements, and regardless of how extensive EPA's own requirements for labeling are in any given area or for any given pesticide. States simply can't impose their labeling requirements under FIFRA. Preemption under the MDA turns on whether FDA has established device-specific requirements. Preemption under FIFRA turns on whether a state-imposed duty operates as a restriction on a pesticide's use or sale (which is expressly allowed under section 136v(a)) or as a requirement for labeling or packaging (which is preempted by section 136v(b)).

The distinction between the MDA and FIFRA is obvious when one pauses to consider whether the fact that EPA does not review efficacy data prior to registration and label approval has any impact on what actions state *regulatory agencies* can take. It is highly unlikely that even ATLA would take the position that, because EPA doesn't review efficacy data for pesticides, state agencies are free to command pesticide manufacturers to place certain warnings regarding crop damage directly on the labels. Whether EPA reviews efficacy data or not, states still cannot impose positive requirements on crop damage disclosure in labeling. That is not the case with the statute at issue in *Medtronic*, where state agencies remain free to impose device-specific positive regulations absent a device-specific requirement from FDA.

The failure in general of lower courts to consider whether their FIFRA preemption analyses make sense when applied to positive enactments, or even to consider whether that matters, is the most striking feature of the FIFRA preemption landscape. Lost in the revelation that the word "requirements" in section 136v(b) applies to common-law damages actions is the fact that section 136v should not produce a greater limitation on state "regulation" by common-law damages actions than positive regulations. It is plain as day that the Eleventh Circuit's forbidden inquiry test cannot be applied to Florida's regulatory agencies. If the state of Florida takes a hard look at an EPA-approved pesticide label and decides that it doesn't do enough to protect human health, Florida is free to restrict the pesticide's use to certified applicators (section 136v(a)), although Florida is not free to command a label change (section 136v(b)). That's the plain meaning of FIFRA section 136v.

It is also plain as day that the fact that EPA does not review efficacy data has no impact on what any state agency can do. They are free to restrict uses and ban pesticides. It makes no difference at all whether the restriction or ban is for reasons related to human safety (for which EPA reviews data) or for reasons related to crop damage (for which EPA does not review data). States are not free to impose labeling requirements. It makes no difference whether the desired label requirement is intended to protect humans or to protect crops. This Court does not miss the obvious implications or potential inconsistencies of its holdings, and therefore this Court's analysis in *Bates* will impact the Eleventh Circuit's holding in this case, whether 50,000 plaintiffs lawyers see it that way or not.

III. *Conclusion*

Respondents' opposition to certiorari does not make any attempt to undercut the central arguments for granting the petition: (1) There is confusion among the lower courts about whether and when FIFRA preempts design defect claims, and (2) the factual allegations and state-law setting of this case make it an ideal instrument for resolving this confusion. Respondents opposition is remarkable only for its failure to address these points.

Respectfully submitted,

Stuart Calwell
Counsel of Record
The Calwell Practice
Law and Arts Center West
500 Randolph Street
Charleston, West Virginia 25302
(304) 343-4323

Alex McLaughlin
The Calwell Practice
178 Chancery Row
Morgantown, West Virginia 26505
(304) 291-5223